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## **AFTER 51 YEARS, MONTEFIORE EINSTEIN CANCER CENTER EARNS THE COMPREHENSIVE DESIGNATION**

Montefiore Einstein Cancer Center can now add the word “Comprehensive” to its logo.

→ PAGE 5

**CAPITOL HIL**  
OBSTACLES CLEARED FOR  
BERTAGNOLLI'S CONFIRMATION  
AS NIH DIRECTOR

→ PAGE 13

**IU SIMON'S HEALTHY BREAST  
TISSUE BIOBANK NOW SEEKS  
TO UNDERSTAND HOW BREAST  
CANCER DEVELOPS—IN MEN**

→ PAGE 15

**GUEST EDITORIAL**  
THE INSINUATION THAT  
ASTROTURF CAUSES GBM HAS  
NO BASIS IN SCIENCE

→ PAGE 19

**OBITUARY**  
DAVID ALBERTS, FOUNDING  
MEMBER OF THE UNIVERSITY OF  
ARIZONA CANCER CENTER, DIES  
AT 83

→ PAGE 22

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# In this issue

---

## COVER STORY (CONVERSATION WITH THE CANCER LETTER)

- 5** After 51 years, Montefiore Einstein Cancer Center earns the Comprehensive designation

---

## CAPITOL HILL

- 13** Obstacles cleared for Bertagnoli's confirmation as NIH director

- 
- 15** IU Simon's healthy breast tissue biobank now seeks to understand how breast cancer develops—in men

---

## GUEST EDITORIAL

- 19** The insinuation that AstroTurf causes GBM has no basis in science

---

## OBITUARY

- 22** David Alberts, founding member of the University of Arizona Cancer Center, dies at 83

---

## IN THE ARCHIVES

- 27** In 1971, Chris Lundy had minute odds of survival. He is now the longest living BMT recipient at the Hutch

---

## IN BRIEF

- 29** UK Markey attains Comprehensive designation

- 29** AACR forms Cancer Centers Alliance to foster collaboration among cancer center leadership

- 30** Dana-Farber, Beth Israel Deaconess plan to build free-standing inpatient cancer hospital

- 31** City of Hope receives \$100M gift from Panda Express founders to create national integrative oncology program

- 32** AACI publishes report on staff retention at clinical trials offices

- 32** KU establishes four-state Heartland Consortium as part of All of Us Research Program

- 33** Fred Hutchinson granted \$38.7M to serve as national coordinating center for Asian American, Native Hawaiian & Pacific Islander health studies

- 34** Emory Winship receives \$24.8M from ARPA-H for mRNA therapeutics project

- 35** Winship's Suresh Ramalingam receives IASLC award for contributions to thoracic cancer research

- 35** Ajay K. Nooka named associate director for clinical research at Winship

- 36** Michael J. Zelefsky named director of brachytherapy, vice chair for academic and faculty affairs at NYU

- 36** Navid Hafez named director of precision medicine and thoracic oncology at the Angeles Clinic

- 37** Mehran Habibi named director of breast surgery for Northwell's Staten Island University Hospital
- 37** Avi Srivastava named assistant professor at Wistar
- 38** Sara Small named assistant professor at Fox Chase
- 38** Amelie Ramirez Wins AACI Cancer Health Equity Award
- 38** Jonathan Licht and Keith McCrae to lead new *Blood* specialty journals
- 39** Eric Kmiec named editor in chief of *Gene and Genome Editing*
- 40** MUSC Hollings head and neck team awarded \$3.5M to reduce delays in care
- 41** UCLA researchers awarded \$2.5M from DoD to develop brain cancer treatment
- 41** Moffitt, pCare partner to bring interactive patient care to Moffitt Cancer Center McKinley Hospital
- 41** Jersey Shore University Medical Center to establish phase I clinical trials unit

---

#### FUNDING OPPORTUNITIES

- 42** FDA opens application for Orphan Products Clinical Trials Grant Program
- 42** UF Health receives \$100k gift from Lyrics for Life for pediatric cancer research

#### THE CLINICAL CANCER LETTER

---

#### CLINICAL ROUNDUP

- 43** University of Arizona Cancer Center's "Scientific Cafés" provide novel outreach
- 43** Lung-MAP master protocol expands trial access
- 44** OneOncology finalizes 25 oncology and hematology pathways
- 45** Six-year outcomes from phase III CheckMate-227 show durable long-term survival with Opdivo + Yervoy in first-line treatment of mNSCLC
- 45** Intensity-modulated radiation therapy provides long-term benefits in NSCLC
- 46** Rybrevant drug combo demonstrates durable PFS in second-line EGFR-mutated NSCLC in CHRYSALIS-2 cohort
- 46** UC Irvine-led study links low-dose radiation to higher cancer risk
- 47** Kisqali reduced the risk of cancer recurrence while maintaining QOL in phase III study

- 47** Nivolumab + ipilimumab more effective in immunotherapy-resistant melanoma than ipilimumab alone
- 48** Combination immunotherapy treatment effective before lung cancer surgery, phase II study shows

- 50** Enhanced recovery program successfully reduced opioid use after pancreatic cancer surgery
- 50** Investigators devise test to identify brain tumors from cerebrospinal fluid
- 51** Vitamin C, D supplements led to fewer complications in AML, no OS benefit
- 52** Blocking proteins could pull the plug on power for colon tumors
- 52** Sylvester researchers help identify mechanisms by which MM escapes targeted immunotherapy
- 53** Study suggests immune system plays role in extended PFS in MM
- 54** Gene therapy study identifies potential new treatment for liver cancer
- 55** Wistar researchers identify potential target for gastric cancers associated with Epstein-Barr Virus

---

#### DRUGS & TARGETS

- 55** FDA approves Akeega for BRCA-positive metastatic castration-resistant prostate cancer
- 56** FDA approves new and updated indications for Temodar under Project Renewal
- 57** FDA, Flatiron Health renew five-year research collaboration on real-world data
- 57** Pierre Fabre Laboratories acquires Vertical Bio

A portrait of Edward Chu, MD, MMS, a middle-aged man with short grey hair and glasses, wearing a dark suit, light blue shirt, and striped tie. He is smiling and looking directly at the camera. The background is dark and out of focus.

## After 51 years, Montefiore Einstein Cancer Center earns the Comprehensive designation

**Edward Chu, MD, MMS**

*Director, Montefiore Einstein Comprehensive Cancer Center;  
Vice president for cancer medicine, Montefiore Medicine,  
Carol and Roger Einiger Professor of Cancer Medicine,  
Professor of oncology, medicine, and molecular pharmacology, Albert Einstein College of Medicine*

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Chu spoke with  
Paul Goldberg, editor and  
publisher of The Cancer Letter.

A



CONVERSATION WITH  
THE CANCER LETTER



Diversity, equity and inclusion are critically important in order to have a successful cancer center, academic institution, medical school, and health system. You need to have the perspectives of the different groups.



Montefiore Einstein Cancer Center can now add the word “Comprehensive” to its logo.

The Bronx-based institution has become one of 56 Comprehensive Cancer Centers in the U.S. The road to the designation was long, as the center was the fourth to receive NCI-designated status—in 1972.

While that’s likely the longest path to the highest level, Comprehensive, designation, there is another, perhaps more significant, metric: in 2019, the institution’s programs were at such a low point that NCI in effect placed it on probation, giving it just three years of funding.

With designation in the balance, the institution put together an exceptionally strong recruitment package and convinced Edward Chu, a long-time member of the External Advisory Board, to take the job of cancer center director. Chu was also named vice president for cancer medicine at Montefiore Medicine (*The Cancer Letter*, Oct. 23, 2020), with additional responsibilities across the entire cancer service line.

In an administrative change, the institution that had been known as Albert Einstein Cancer Center for more than half a century was renamed Montefiore Einstein Cancer Center.

“After I took over as the director, I met with NCI senior leaders to explain to them what the institutional investment was as part of my recruitment to be the new director of the cancer center,” Chu said to *The Cancer Letter*. “I think they were very impressed with the institutional support and commitment, which was truly exceptional—really transformational.”

The institutional support commitment for a nine-year period starting in 2020 was \$236 million. It is a commitment that survived the COVID-19 pandemic,

which cost the health system about \$1.5 billion.

As a former EAB member, Chu knew what the cancer center needed—and that change had to happen fast.

“It’s actually less than one review cycle, because, as you know, I took over on Oct. 1, 2020. So, our application went in at the end of September 2022. That’s only two years,” Chu said. “And at the time of our NCI site visit, it was just under 2.5 years.”

Chu appointed 10 new members to his senior leadership team as well as eight new program leaders.

“One of the things that my mentor, Vince DeVita, embedded in me was that in order to be successful as a leader, you need to have responsibilities, authorities, and resources/finances,” Chu said. “If you’re missing any one of those elements, it’s going to be very difficult to be successful.”

“And so, I had the responsibilities—obviously significant as center director—but I had the authorities, and I had the resources, and the commitment from the institution.”

The January 2023 NCI site visit went well.

“The review team as well as the NCI parent committee, I believe, commented on the level of truly exceptional institutional support and commitment. This really transformed the cancer center, enabling it for the first time in quite a while to recruit new faculty, build up new shared resources, and nurture developmental pilot project funding. All of this was a big change given that at the time of the last review, the institutional support commitment was not viewed as being very strong,” Chu said.

In a related development, The University of Kentucky Markey Cancer Center

has attained the NCI Comprehensive Cancer Center designation, the institution announced Sept. 15.

Montefiore's Chu spoke with Paul Goldberg, editor and publisher of *The Cancer Letter*.

**Paul Goldberg:** Well, Ed, congratulations. It's quite a feat, getting the Comprehensive designation.

**Edward Chu:** Obviously, we were thrilled that the NCI site visit team, the NCI [Parent Committee](#), and the NCI senior leadership approved our request to be designated a Comprehensive Cancer Center for the first time in our history.

As you know, we are the fourth oldest NCI-designated Cancer Center, having been designated back in 1972. Last year, in 2022, we celebrated our 50th year as an NCI-designated Cancer Center.

So, for us, it really was a huge deal to be able to add on NCI-designated Comprehensive Cancer Center.

It's an even a bigger feat, because—let's turn the clock back to 2019, your review then—how did that go?

**EC:** That review didn't go so well. That was probably the low point of the Cancer Center. At that time, we actually received the worst score in our history. And in essence, we were placed on probation—probation meaning we were given only three years of funding, and with reduced funding.

Truthfully, were it not for the generosity and good will of the NCI senior leaders who believed that, because of our particular catchment area in the Bronx County in New York—the most racially, ethnically diverse population in the

country as well as one of the country's poorest counties—our cancer center had a special place in the NCI Cancer Centers Program.

So they kept us afloat.

I especially think they were thrilled to see that our review had gone so well.

So, let me just point this out: You went from the kind of the back of the room to top-rated, and moved up to Comprehensive—in one review cycle.

**EC:** It's actually less than one review cycle, because, as you know, I took over on Oct. 1, 2020. So, our application went in at the end of September 2022. That's only two years.

And at the time of our NCI site visit, it was just under 2.5 years.

Everything was on an accelerated path, if you will.

Has this happened in the history of the world—since Creation?

**EC:** I don't know. But [Henry Ciolino](#), PhD, director of the NCI Cancer Centers Program and a person who obviously knows the history well, was telling me at our recent NCI cancer center-directors meeting in Gaithersburg, MD, in the middle of May, that our center had the greatest single improvement in one cycle.

But really you're talking about going from the probation... Were there no-cost extensions?

**EC:** The NCI leadership was terrific.

They had given our cancer center, three years of reduced funding. And, after I took over as the director, I met with NCI senior leaders to explain to them what the institutional investment was as part of my recruitment to be the new director of the cancer center.

I think they were very impressed with the institutional support and commitment, which was truly exceptional—really transformational.

The review team as well as the NCI parent committee, I believe, commented on the level of truly exceptional institutional support and commitment. This really transformed the cancer center, enabling it for the first time in quite a while to recruit new faculty, build up new shared resources, and nurture developmental pilot project funding.

All of this was a big change, given that at the time of the last review, the institutional support commitment was not viewed as being very strong.

Can you tell me what the level of support was?

How did it happen?

You've gotta have the money, then you gotta have the leadership; right? Money alone isn't enough. Leadership alone may be enough.

How much did they give you?

**EC:** What I think is unprecedented is that while the institutional support goes for five years, which is our next funding period, Montefiore Einstein leaders, and in particular Montefiore Medicine President and CEO [Philip Ozuah](#), agreed to go one year beyond the five-year funding period—out to 2029.



When you look at the institutional support commitment for a nine-year period, it's \$236 million.

**Wow.**

**EC:** So, that's pretty significant.

Obviously, you need to have the funds to be able to do all that's necessary for an NCI-designated Cancer Center.

The other important piece was that prior to my arrival, David Goldman did an exceptional job under the circumstances in receiving very restricted financial support from the institution.

During David's 25-year tenure as cancer center director he only reported to the dean of the Albert Einstein College of Medicine. He had no reporting line to hospital leadership and the CEO.

One of the real issues or sticking points when I was negotiating for this position was that I felt it was critical for me not only to report to the dean of the Albert Einstein College of Medicine but to also have a direct reporting line to the CEO and president of Montefiore Medicine.

And I have to say, both the dean and the CEO understood and appreciated the importance of that dual reporting line.

**Still, how did you do it all in that short a time?**

**EC:** I was extremely fortunate to have a tremendous team.

This is all about the team effort, and one cannot do it alone. Obviously as the cancer center director, I help to direct the strategic priorities.

But I was very fortunate.

One of the criticisms at the time of the last review was that there was a lack of new blood, if you will, in both the senior leadership and program leadership.

Over the course of the last two years, I appointed 10 new leaders into my senior leadership team.

And I appointed 8 new program leaders (ultimately nine in all).

I was very fortunate to have Lauren Hackett serve as my deputy director of administration and associate vice president of cancer medicine.

Lauren has had a long career as an executive administrator, having worked at three NCI designated cancer centers, and most recently, as chief operations officer at the Allen Institute in Seattle, WA. I first met her when we were at the Yale Cancer Center, where she was Vince DeVita's deputy director for administration.

When I called her up and asked if she knew of anyone who could join me as the Cancer Center administrator, she said that she would be very interested in working together, serving the Bronx community. It was perfect timing and a natural fit since they were planning to return to the East Coast.

And that really helped set the stage, because she has tremendous experience and in-depth knowledge of how a Comprehensive Cancer Center needs to operate. Having her onboard was hugely important.

I appointed Ulrich Steidl, who had been the program leader for our Cancer Biology Program, as the cancer center's deputy director and associate director for basic science.

And then I appointed another deputy director to oversee community engagement and cancer health equity—Alyson Moadel-Robblee.

In addition to these individuals, I appointed 7 other senior leaders. As you well know, it's very important is to have an effective leadership team.

You have to allow your senior leaders to go out and do what's necessary to implement the strategic priorities of the cancer center. I have to say, they did an incredible job.

Obviously, we were under a lot of pressure. We came back to be renewed a little bit quicker than some people thought we should have, but I thought that we were pretty well-positioned given all of the changes that had taken place, and that so many of the priorities emerging from our strategic plan had already begun to be implemented

**You grew up in the system. You know the system. Did you ever have moments when you look at yourself in the mirror and say, "Oh my God, what did I get myself into?"**

**EC:** No. Because as you say, Paul, I've been in the business for such a long time, initially at the Yale Cancer Center and then at the UPMC Hillman Cancer Center. And I was very fortunate to have had tremendous mentors.

At Yale, Vince DeVita really helped to show me the way, and then at the UPMC Hillman Cancer Center, it was Nancy Davidson and then Bob Ferris. I've been very fortunate over the years to have great mentors.

Serving on the NCI Parent Committee that reviews NCI Cancer Centers and having served on so many external advisory boards for NCI-designated Cancer Centers has given me a truly in-depth understanding of how Cancer Centers need to be run in order to be successful.

**So, basically, you were very comfortable with the task, and just went through it methodically, with full understanding of the strategy and the day-to-day; right? Is that how it really worked?**

**EC:** I think I may have told you this. My official start date was October 2020.

In the summer of 2020, before I came on board, we engaged Beverly Ginsburg and her team at Huron Consulting to begin our strategic planning process. We worked with our External Advisory Board, the cancer center's senior leaders, program leaders, and shared resource directors to really get into the nuts and bolts of a strategic plan.

That process took about eight months in all.

And it meant that by March or April of 2021, we had a strategic plan that detailed the priorities and milestones for the Cancer Center.

**This was not an empty words strategic plan? This was an actual strategic plan?**

**EC:** This was a real strategic plan.

I am particularly proud of this plan [because], unlike most plans that I've seen, which are very static in nature, they're usually for five years.

This is really a living, breathing, strategic plan.

We have nine strategic working groups, each structured with chairs, co-chairs, and members all working to continually tweak, modify, and improve and enhance the goals and priorities of that working group.

At the time of the site visit, the only comment was that given that about 60% of the strategic plan had already been achieved in under two-and-a-half-years, "perhaps our strategic plan wasn't ambitious or aggressive enough."

My response was that even before I started as cancer center director, we had begun to think about what our strategic priorities should be--so we hit the ground running. Everyone, from senior leaders to program leaders and shared resource directors, have been working at warp speed to implement the strategic priorities.

About a month after our site visit, we held our second strategic planning retreat, at which time, each of the groups went through what they had outlined the year before and tweaked and updated the plan.

I think this is actually quite different than most strategic plans that I've seen at most other NCI cancer centers.

**How helpful was the EAB in this process?**

**EC:** The EAB was tremendously helpful.

Given that there was a significant turnover in senior leaders and program leaders, I thought it was also important to get a new crew of EAB members.

Four EAB members stayed on for continuity, and I appointed 10 new members. All have tremendous experience as NCI cancer center directors, program leaders, or shared resource directors.

I have to say, their input and advice was invaluable, especially in two areas that I had identified.

One was reorganizing and restructuring our clinical research operations and in-

frastructure. We actually convened two mini-ad hoc EAB meetings, just focused on clinical research.

The other area, which has become increasingly important for all NCI Cancer Centers, is community outreach engagement and catchment area research.

We convened two mini-ad hoc EAB meetings focused on this area, with members with expertise in COE and population science and catchment area research to review our progress and to give advice.

**There had to be a point in there where a decision was made: "We're not just gonna try to stay afloat, which is keeping the designation, but we'll go up and seek Comprehensive." What the heck? How how'd you make that decision? What was the thinking?**

**EC:** I have to say that was my thinking from (almost) Day One.

Since I had served on the Einstein Cancer Center EAB for the previous 15 years, I had a deep understanding and appreciation of the strengths and the weaknesses of the cancer center.

One of the things that my mentor, Vince DeVita, embedded in me was that in order to be successful as a leader, you need to have responsibilities, authorities, and resources/finances. If you're missing any one of those elements, it's going to be very difficult to be successful.

And so, I had the responsibilities—obviously significant as center director—but I had the authorities, and I had the resources, and the commitment from the institution.

So, I felt we had all the pieces, but not all of them were aligned and integrated.

Here's a perfect example: for 51 years, our cancer center was called the Albert Einstein Cancer Center. And about a year or so ago, we made the decision to rename it Montefiore Einstein Cancer Center.

This re-naming highlights the tight alignment and integration of the academic side from the Einstein College of Medicine and the clinical care health-care delivery and outreach part of the Montefiore Health System.

**We are also forgetting COVID. We haven't even talked about it. You came in right at the height of COVID, when the health system [had] lost a massive amount of money taking care of patients.**

**EC:** Again, we were extremely fortunate. Our home in the Bronx was at the epicenter of COVID-19 pandemic at its peak. At that point, our hospital system (Montefiore) had 2,100 beds used only for COVID patients.

Pretty dramatic. And in the two years that COVID hit the Bronx and Montefiore Health System particularly hard, the health system lost \$1.5 billion.

**And they still found the money to fund you?**

**EC:** Again, to the credit of Dr. Ozuah and the dean of Albert Einstein College of Medicine [Gordon Thomaselli](#), they created a carve-out for us, immunizing the cancer center from the financial hardships that both institutions were experiencing.

We were in an extraordinarily unique position to use the resources that had been committed to us moving forward. They obviously appreciated the serious

position that the cancer center was in at the time of the last review.

**So, what happens next?**

**EC:** Even though we have been successfully renewed and now have Comprehensive status, there's much work to be done.

We're very proud of our exceptional basic laboratory science, but there are still areas that we want to build on in terms of cancer therapeutics and drug development, cancer and aging, and understanding cancer tumor dormancy and the microenvironment. We also want to continue to build on our understanding of cancer disparities in our Bronx community.

One area where we really need to focus more of our efforts is on clinical trials, and in particular, investigator-initiated, bench-to-bedside clinical trials.

COVID negatively impacted our ability to enroll patients in clinical trials, given that the pandemic hit our Bronx patients very hard.

As a result, even when other centers around the country were opening and starting clinical trial enrollments, our underserved Bronx community was reluctant and hesitant to get involved. And because we are located in one of the poorest, financially disadvantaged communities in the country, our cancer patients face a tremendous number of health stressors (social determinants of health) compared to most other places.

When I compare how easy or difficult it is to enroll a patient onto a clinical trial at our cancer center as opposed to places like Pittsburgh or Yale, it's about three times harder. In other words, having one of our patients go into a clinical trial is about as challenging as enrolling up to three patients somewhere else.

It's just tremendously different.

**There are a couple of cancer centers now that I can think of right off the bat that are on probation or heading that way. What's your advice to them? Because you really made a save.**

**EC:** I think the key is to work closely with the institutional leaders, because at the end of the day, you need to have the institutional support, institutional commitment, and the financial resources to be able to invest in the cancer center.

The other ingredient is leadership, but it is not just on the part of the cancer center director but on the part of the senior leadership team, the program leaders, the shared resource directors, and it's all of those leaders working together as a well-coordinated, cohesive team that aligns and implements—and follows through with the strategic priorities of the cancer center.

**One last thing: the Supreme Court ruling on affirmative action. How is that going to affect DEI?**

**EC:** I think that that vote by the Supreme Court was extremely disappointing and concerning. As you know, as it relates to the NCI Cancer Centers Program, there is now such a focus on the principles of diversity, equity and inclusion (DEI), and just as COE now has become such an integral part of all elements of the NCI Cancer Centers Program, I believe DEI will also be as tightly integrated and incorporated in all elements of the NCI Cancer Centers review.

If I had to read the tea leaves, just like COE and education training (CRTEC) are two of the fundamental elements for comprehensiveness of a cancer center, I would not be surprised to see

DEI become one of the core elements for consideration of Comprehensive designation.

There's going to be more and more focus placed on DEI. I think we even talked about this issue in our very first interview, that diversity, equity and inclusion are critically important in order to have a successful cancer center, academic institution, medical school, and health system. You need to have the perspectives of the different groups.

And so, when we talk about the pathway programs—the pipeline programs that all of the other NCI cancer centers are developing, they are starting from high school on to college, medical school postdoc training, and fellowship training faculty.

The Supreme Court decision is a tremendous blow to our ability to build that type of pathway program.

**And you are the right person to ask, because your center is in a place where there is no white majority.**

**EC:** It's interesting—Einstein was founded on the principles of social justice. It was a social mission.

”

Albert Einstein only agreed to give his name to the medical school if the commitment was made to admit medical students with no prejudice to race or creed. And Montefiore was started on a social justice mission to serve the underserved community in the Bronx.

So for our cancer center, DEI is deeply engrained in what we do every day.

**So, what does the Supreme Court ruling going to do to you, if anything? My understanding was that was really for college; right?**

**EC:** Because we are a medical school and are not affiliated with a university or college—it hopefully won't impact our ability to continue the principles of diversity, equity, inclusion, and affirmative action.

**Is there anything we've missed? Anything I forgot to ask?**

**EC:** Thanks so much for meeting with me. It's been a lot of hard work. But I have to say, it's been fun. It's been rewarding. And I've been extraordinarily proud of how our team has come together and worked for a common cause and mission.

**Well, again, congratulations.**

”

**It's been a lot of hard work. But I have to say, it's been fun. It's been rewarding. And I've been extraordinarily proud of how our team has come together and worked for a common cause and mission.**

## CAPITOL HILL

# Obstacles cleared for Bertagnolli's confirmation as NIH director

## Senate HELP Committee schedules hearing

By Matthew Bin Han Ong

A confirmation hearing for NCI Director Monica Bertagnolli will take place sometime in October, said Sen. Bernie Sanders (I-VT), chairman of the Senate Health, Education, Labor, and Pensions Committee.

“I look forward to meeting with Dr. Bertagnolli to discuss what she is prepared to do at the NIH to substantially lower the outrageous price of prescription drugs in America,” Sanders said in a statement Sept. 8.

Sanders had previously vowed to oppose Bertagnolli's nomination—and potentially other White House nominees—unless the administration puts together a plan to lower drug prices.

Another opponent of Bertagnolli's confirmation, Sen. Elizabeth Warren, has withdrawn her opposition after Bertagnolli pledged not to seek employment of advisory roles at any large pharmaceutical company for four years after concluding her stint as NIH director.

“I am willing to voluntarily extend the recusal period from two years to four years for all particular matters involving companies with which I have a previous working relationship,” Bertagnolli said in a statement Aug. 29. “If confirmed



as NIH director, I will also further commit for four years following my tenure to not seek employment with or compensation from, including as a result of board service, any pharmaceutical company with annual revenues at or above \$10 billion.”

As the NCI director, Bertagnolli didn't have to go through confirmation by the Senate. The NIH job requires confirmation.

President Joe Biden announced May 15 his intent to nominate Bertagnolli to the NIH directorship (*The Cancer Letter*, [April 21](#), [May 19](#), 2023).

“Dr. Bertagnolli has advanced my Cancer Moonshot to end cancer as we know it,” Biden said at the time. “[She] is a world-class physician-scientist whose vision and leadership will ensure NIH continues to be an engine of innovation to improve the health of the American people.”

As the world's biggest funder of biomedical research, it's unclear whether NIH—and, by inference, the NIH director—has authority to address drug prices.

“The NIH has done excellent work to research and develop new prescription drugs and treatments that have improved the lives of the American people and people throughout the world,” Sanders said Sept. 8. “But it has not done a good job in making sure that prescription drugs developed with taxpayer funding are sold at a reasonable price.”

On Aug. 29, the Centers for Medicare and Medicaid Services published a list of the first 10 drugs selected for price negotiations under the Medicare Part D program. That list includes only one oncology drug: ibrutinib (Imbruvica), a tyrosine kinase inhibitor (*The Cancer Letter*, [Sept. 8](#), 2023).

The Department of Health and Human Services Sept. 8 reached a deal with the pharmaceutical company Regeneron to use reference pricing to limit the list price of future next-generation monoclonal antibodies for COVID-19 prevention.

A clause in the agreement that describes Regeneron's commitment to ensuring that the list price of new products in the U.S. will be equal to or less than its retail price in comparable markets globally follows:

If Regeneron commercializes a product in the United States for prevention of SARS-CoV-2 comprised solely of a COVID-19 therapeutic for which BARDA invests [a minimum amount or more] under this Agreement, then, subject to applicable law, the list price (at wholesale acquisition cost) for commercial sales of such product in the United States following full licensure of the product, shall be substantially equivalent to or less than the approved price for commercial sales in High Income Countries outside of the United States; provided that such sales are comparable sales taking place within the same time period.

Regeneron is permitted to take into account all relevant factors in determining whether sales are comparable sales, including volume commitments, timing of purchase and supply, the terms and conditions of purchase and supply, market conditions and epidemiology of SARS-CoV-2.

“I welcome the Biden administration's announcement today that if Regeneron, through a \$326 million contract recently signed with HHS, successfully develops a next generation monoclonal antibody

for COVID-19 prevention, the list price of this drug must be equal to or lower than the price in other major countries,” Sanders said in a statement Sept. 8.

“In light of the recent actions taken by HHS and a commitment I received from the White House to keep working to lower the price of prescription drugs, the HELP Committee will be holding a hearing on the nomination of Dr. Monica Bertagnolli to be the director of the National Institutes of Health in October.”

“

I am willing to voluntarily extend the recusal period from two years to four years for all particular matters involving companies with which I have a previous working relationship.

”

—Monica Bertagnolli

# IU Simon's healthy breast tissue biobank now seeks to understand how breast cancer develops—in men

By Matthew Bin Han Ong

The world's only biobank that collects healthy breast tissue is once again taking the lead to fulfill another unmet need in breast cancer research: collecting tissue from men to understand how male breast cancer develops.

Founded in 2007, the Susan G. Komen Tissue Bank at the Indiana University Melvin and Bren Simon Comprehensive Cancer Center was designed to define “normal” breast cancer tissue in diverse populations of women at a time when existing measures for collecting and characterizing normal tissue were not reliable (*The Cancer Letter*, [Oct. 27, 2017](#)).

The Komen Tissue Bank is contributing to a more complete understanding of normal, which can help define what constitutes abnormal in breast cancer. The abnormalities, relative to normal breast tissue, can reveal clues to the risk factors and the causes of breast cancer as well as the pathways that cause disease to progress.

Nearly twenty years after its founding, with new leadership and funding, the tissue bank is focused on meeting

a demand for studying breast tissue from men. Whereas women used to be underrepresented in medical research overall, in breast cancer research, men are now underrepresented.

“I’ve only been here for a year, but we’ve been receiving more and more requests for tissue from men,” Michele Coté, director of the Komen Tissue Bank, said to *The Cancer Letter*. “We started really talking as to whether or not this would be something that we could do. And as it turns out, we’ve been able to do it successfully now 31 times.”

Coté joined the Komen Tissue Bank in September 2022. Prior to that, she was a tenured professor at Karmanos Cancer Institute, where her research focused on molecular cancer epidemiology and benign breast diseases.



**Michele Coté, PhD, MPH**

Director, Susan G. Komen Tissue Bank,  
Dr. Carrie Ann Glasscock West  
Chair in Breast Carcinogenesis,  
Indiana University Simon  
Comprehensive Cancer Center

Coté traces her decision to move to IU Simon Comprehensive Cancer Center to a call she received from Anna Maria Storniolo, then executive director and co-founder of the tissue bank (*The Cancer Letter*, [Oct. 27, 2017](#)).

“I had been aware of the Komen Tissue Bank for approximately 10 years prior to that time, and in 2016, we actually hosted a tissue collection event on site in Detroit. And it was fantastic. We collected tissue from 189 women over the course of about six hours,” said Coté. “Anna Maria called in November 2021 and said, ‘I’m looking at retiring, and the first thing that I want to do before I can comfortably retire is find somebody to take over as the director.’

“I was not necessarily looking to move, but I knew what an incredible resource the Komen Tissue Bank was. I’ve really understood the importance of normal tissue and the importance of being collaborative, and some of the fundamental, core beliefs at the tissue bank are in line scientifically with my interests and my overall beliefs as to how we should be doing science these days.”

Thanks in part to philanthropy, investigators at IU Simon Comprehensive Cancer Center have an infusion of resources to accelerate research on male breast cancer. The Matthew Bowman Breast Cancer Research Fund was [established](#) by Pat Buntrock in memory of her son, who died from metastatic breast cancer in 2021. The cancer center also received a gift from the [Catherine Peachey Fund](#).

The tissue bank started its first collection for men with a small pilot study of 10 participants in November 2022. The researchers gathered 21 more samples in June 2023, and have planned two more 2023 collection events on Sept. 30 and Nov. 11.

“I would love to see that by the end of 2024, we’ve got 100 men, and then build

from there. We’re trying to catch up a little bit after the pandemic shutdowns where we couldn’t do tissue collection events,” Coté said. “So, instead of doing two or maybe three collections a year, we’re pushing a little bit more to get to four. And I think if we could get around 20 men for every tissue collection we have, that’s a good goal.”



I knew what an incredible resource the Komen Tissue Bank was. I’ve really understood the importance of normal tissue and the importance of being collaborative, and some of the fundamental, core beliefs at the tissue bank are in line scientifically with my interests and my overall beliefs as to how we should be doing science these days.



– Michele Coté

The Komen Tissue Bank is looking for partners and collaborators to host collection events, anywhere in the U.S. or worldwide.

“We bring all the supplies, we set up a laboratory on site. We really bring everything, because we want to make sure that everything is being collected and processed in an absolutely standardized manner,” Coté said. “So, that’s why we bring all of our personnel in. We do all of the training; we can help with outreach and engagement to different populations.

“We really need to be able to collect at different sites, because Indiana doesn’t have the diversity of a lot of other places in this country. So, we definitely travel. I believe we’ve done seven out-of-state events and 11 out-of-town events, and now that the pandemic restrictions have lifted somewhat, we’re definitely looking for partners across the U.S. and, and really across the globe.”

There’s an added benefit: partner institutions get to keep some of the samples and data.

“If I put on my Detroit collaborator hat [from my time in Michigan], they left us a portion of all of the samples. We got blood from everyone we collected, the tissue, as well as all of the associated data,” Coté said. “What that allows an institution to do then is, you’ve got all these samples that you can use for pilot studies, and hopefully as your pilot studies are working out, you’ve got the entire tissue bank at IU that can be used for larger studies, for replication, for validation.

“And so, it can be a really powerful thing for a center that wants to invest a little bit more in breast cancer research.”

## A focus on diversity in tissue collection

The Komen Tissue Bank is relying on its experience in reaching out to underrepresented populations to ensure that, from the outset, minority men are



participating in its collection drives. Of note, non-Hispanic Black men experience the highest incidence of breast cancer and death rates compared to men in other racial and ethnic groups.

“One of the fundamentals that the bank was built on was the idea that we would have samples from a very diverse population,” Coté said. “And so, the initial interpretation of that was that we wanted to be sure that the racial and ethnic makeup of our population mirrored what was seen in the rest of the U.S.

“We’ve put a lot of focus on recruiting people into the Komen Tissue Bank who are from historically underrepresented populations.”



**Katherine Ridley-Merriweather, PhD, MA**

*Communication, recruitment, and outreach manager, Biospecimen Collection and Banking Core, Communication and minority outreach coordinator, Susan G. Komen Tissue Bank, Indiana University Simon Comprehensive Cancer Center*

Key to these efforts is Katherine Ridley-Merriweather, the communication, recruitment, and outreach manager of the cancer center’s Biospecimen Collection and Banking Core, of which the Komen Tissue Bank is part.

“I didn’t want to play catch-up like I had to do with the women,” Ridley-Merriweather, who conducts minority outreach for the tissue bank, said to *The Cancer Letter*. “When I began working with the Komen Tissue Bank in 2011, the great majority of tissue donors were white women. I had to learn to understand why the Black and Brown women were not coming. It took a while to develop appropriate strategies to educate and recruit them.”

Over the past 12 years, Ridley-Merriweather has significantly increased minority participation in the tissue bank’s sample collection campaigns.

“It is a myth that Black and Brown people will not participate in clinical trials,” Ridley-Merriweather said. “We absolutely will. The Komen Tissue Bank has 18% Black participation.

“Black men [develop breast cancer] and just like the women, have a much higher mortality rate than members of other racial and ethnic populations. Black men are more likely to get more aggressive forms of breast cancer.

“On collection event day, for a variety of reasons, usually about 20% to 25% of the women who make appointments to donate do not make it in,” Ridley-Merriweather said. “Not so with the men. Only two of the men who had appointments didn’t come, and they called long before their appointment times and said, ‘I can’t make it, I’m sorry.’ All the other men came. Not only were they there, but they were also ridiculously early!”

Collecting normal samples with long-term follow-up allows researchers to study the evolution of breast tissue across diverse populations. This yields a biobank that enables robust interdisciplinary, multivariable analyses—spanning biology, behavioral risk factors, and social determinants of health—to understand the etiology of

breast cancer and inform subsequent interventions.

“You need to be able to integrate all of the data,” Coté said. “So, you need to be able to look at genetics, genomics, some of the personal behaviors or risk factors, and things like family history, reproductive history, and breastfeeding. And then, you also need to be able to incorporate social and economic factors, or even area-level factors, including environmental factors.

“At the tissue bank, we collect all of that information. And that’s what makes having access to this tissue really powerful. In addition to having the tissue, we also collect a blood sample, so having those paired samples too is really critical. Coupled with the mammograms that we collect from women and the follow up, all of those pieces together in one place is incredibly hard to find.

“It’s probably what we’re going to need to do to be able to disentangle the contribution of all the different factors involved in developing breast cancer.”

## Cultural competency in recruitment

Building relationships with minority communities is crucial to build trust, communicate the goals of breast cancer research, and increase participation in studies.

“I don’t do anything without food. Nothing. If I’m holding any kind of event or session and you attend, I’m going to feed you,” Ridley-Merriweather said. “I’m often asking people to come to an information or recruitment event right after work or during lunchtime. The least I can do is feed them. We must honor the populations that we want to recruit. And should they decide not to participate, researchers must not blame them for declining.”

Many non-minority investigators make the mistake of assuming that all patients would feel comfortable in a research study, Ridley-Merriweather said.

“You could be in 10 studies as a safe white person—which the majority in certain types of research certainly can be—but I don’t have those feelings of safety,” Ridley-Merriweather said. “Black and Brown people have certain truths that they are always thinking of and dealing with.

“We have centuries of abuse and lies, so, it’s a great fear that maybe they’re being used as a guinea pig or that they’re not going to be told the truth or that something within research is going to be harmful to them rather than being helpful to them.”

Diverse communities cannot be approached in the same manner, with the same expectations, with the same ideas, or with the same vocabulary. For instance, Hispanic participants might be sensitive to the threat of deportation on a familial or community level, and Asian patients may have concerns about privacy and the stigma associated with breast cancer, Ridley-Merriweather said.

“I can’t tell you how many researchers go into a community they don’t know anything about—this is almost always white men, but not completely—going into a community they know nothing about and think that they can write a message that is going to encourage those people to come do what they want to do,” Ridley-Merriweather said.

“If you have not done your due diligence and studied and researched those populations, you likely are not saying anything they want to hear or anything that’s going to have them feel open to more of what you’re going to say.

“I’m a rock star in a room full of Black women, but not so much in other groups whom I don’t resemble. That’s probably the main thing that I have learned throughout this journey, and that I need to respect and honor those cultural differences.”

## Why a diverse outreach workforce is essential

In a June 29 survey by this publication, most health professionals said they expect that the recent Supreme Court ruling on affirmative action will have a moderate to significant impact on diversity in medical and graduate programs, the oncology workforce, and biomedical leadership—which will adversely impact cancer care and outreach to underserved populations, patient trust, and clinical trial recruitment (*The Cancer Letter*, [June 30, 2023](#)).

Ridley-Merriweather believes that cancer centers and public health organizations need to step up their investments in recruiting a diverse workforce to counteract the chilling effects of this recent Supreme Court decision.

“I hope I’m wrong, but I totally expect diversity levels to tank. Some cancer centers say they don’t have the [research participant] diversity they’re looking for, but don’t understand that increasing the diversity of your medical, research, and support staff is a critical step to achieving the research participant diversity that you say you’re looking for,” Ridley-Merriweather said. “When you have no history of it, it just does not promote trust or a desire to be there.”

Underserved and marginalized communities that experience minority stress undergo epigenetic changes that contribute to increased allostatic load—a cumulative burden of chronic stress and

wear and tear on the body—leading to accelerated biological aging, adverse health outcomes, and reduced life expectancy.

These race-based stressors result in heritable epigenetic markers that can affect health across generations. For example, DNA methylation changes are linked with more chronic pain and depression in African Americans and a vast array of medical and psychiatric illnesses.

Ridley-Merriweather believes that helping Black and Brown people to achieve better health should be simpler. “We want to see people, we want to hear health information from people who look like us, because there is definitely a trust factor in knowing that you’re going to understand me because you are what I am, or you look like me.”



**Black men [develop breast cancer] and just like the women, have a much higher mortality rate than members of other racial and ethnic populations. Black men are more likely to get more aggressive forms of breast cancer.**



– Katherine Ridley-Merriweather



GUEST EDITORIAL

# The insinuation that AstroTurf causes GBM has no basis in science

***The Philadelphia Inquirer series does disservice to brain tumor community***



**Henry S. Friedman, MD**

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The Preston Robert Tisch Brain Tumor Center at Duke*

**Kyle M. Walsh, PhD**

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We see far too many patients with glioblastoma (GBM), an aggressive and almost always fatal malignant brain tumor.

Initial conversations with patients and families faced with this devastating diagnosis typically center on optimal treatment plans, including both standard-of-care therapy (surgical resection, radiation therapy, and multiple courses of temozolomide), and experimental options available through clinical trials.

Further discussions often focus on goals of care and how best to extend survival while maximizing health-related quality of life, but many patients eventually ask a question that lacks a satisfactory response:

“Why did I get this tumor?”

With the exception of ionizing radiation, which accounts for less than 1% of GBM diagnoses, no modifiable environmental or behavioral factors have been convincingly linked with GBM causation. In this regard, GBM is unusual among cancers as even canonical risk factors, like cigarette smoking, have not been shown to modify GBM risk.<sup>1</sup>

Within the neuro-oncology community there is a sense that the GBM patient population may even be enriched for high-achieving and health-conscious individuals. This clinical observation is increasingly supported by emerging research, including prospective cohort data observing that healthier diets are associated with an elevated risk of GBM, and genomic studies linking GBM risk to biomarkers of healthier aging and improved baseline cognitive function.<sup>2-4</sup>

Although an ongoing area of study, decades of epidemiologic research has reached an expert consensus that the causes of GBM are multifactorial, genetically influenced, modified by sex and age, and that the effects of any alleged

environmental toxicants are most likely modest or nonexistent.

Two misleading stories appearing in *The Philadelphia Inquirer*<sup>5-6</sup> have given voice to the unfounded belief that six Philadelphia Phillies players developed GBM as a result of exposure to chemicals used in the manufacture of artificial turf.

We do not begrudge *The Inquirer* for its interest in understanding the causes of GBM, as we have devoted our careers to addressing this very issue. However, by focusing on a sensational and exceedingly speculative exposure, these articles misrepresent the state of the science and do a disservice to the brain tumor community. We hope to remedy that here.

The occurrence of six GBM diagnoses among the more than 500 players on the Phillies roster over a span of several decades reflects an approximately 3-fold higher rate than expected. However, it also reflects a very small dataset, even by the standards used in analysis of “cancer clusters,” which themselves have a long history of over-interpretation.

We also note that GBM incidence is highest in men, in non-Hispanic white individuals, and in those ages 50-75, which is to say that ballplayers from the latter half of the twentieth century exemplify the key GBM demographic. We discussed this potential GBM cluster with the Phillies front office more than two years ago, after a cable news commentator suggested radar speed guns could be responsible.

While three of the six Phillies players diagnosed with GBM were pitchers, radar guns operate in the same electromagnetic band as motion detectors, with frequencies below the visible spectrum and well below that of ionizing radiation (e.g., X-rays).

One of us (KMW) also had multiple conversations with a reporter from *The Inquirer* regarding the notion that per- and polyfluoroalkyl substances (PFAS) that they detected in souvenir sections of the old AstroTurf (purchased on eBay) could be a cause of GBM.

While noting that environmental health concerns around PFAS exposure are based on valid scientific research, we also cited research showing that compounds like PFAS have poor penetrance across the blood-brain barrier and reach the brain at levels 1,000-fold lower than other organs.

Thus, there is little biologic plausibility for a connection between these compounds and GBM, particularly compared to more credible malignancies (e.g., renal or hepatic cancer). While some of this information was included in the first *Inquirer* article, that article was five pages of newsprint and titled “Field of Dread.”

This may garner clicks and sell papers, but it does not represent a balanced presentation of an investigation rife with caveats.

One of us (HSF) was privileged to be the physician for Tug McGraw, who died from a GBM in 2004 at the age of 59.

As Tug’s neuro-oncologist, he is personally aware of the distress and emotional turmoil that this exploitative piece has inflicted on Tug’s wonderful family.

Families who have lost loved ones to GBM should not have their shared tragedies propagandized in articles that are light on scientific facts and heavy on alarmism.

We wholeheartedly agree that more research into GBM causation is desperately needed in order to intercept these tumors early in their clinical course or, ideally, to prevent them from ever

forming. The brain tumor research community is actively engaged in this undertaking, and that work is informed by decades of dedicated effort and well-designed studies that lay a foundation for future discoveries.

There is nothing inherently wrong with evaluating the chemicals referenced in *The Inquirer* article for a possible role in GBM causation. However, given the state of the science, this would represent an injudicious use of the finite financial, personnel, and tissue resources available.

These resources should be allocated to the most cogent and impactful research if we seek to transform GBM prevention and care.

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By focusing on a sensational and exceedingly speculative exposure, these articles misrepresent the state of the science and do a disservice to the brain tumor community.



## OBITUARY

# David Alberts, founding member of the University of Arizona Cancer Center, dies at 83

*By Lisa M. Dahm and Mark Anthony Febbo*

As a founding member of the University of Arizona Cancer Center, David Alberts, MD, and his influence on cancer research epitomizes Isaac Newton's famous quote, "If I have seen further, it is by standing on the shoulders of giants."



“Dr. Alberts was a great beacon of innovation and scientific exploration for the center,” said University of Arizona Cancer Center Director Joann Sweasy. “He was a source of encouragement for me in taking on the role of director, and he helped the center evolve to meet the specific needs of our community.”

Alberts, who died on July 29 at the age of 83, not only assisted in creating the Arizona Cancer Center in 1976, but he also developed the center’s Cancer Prevention and Control Program into one of the top programs in the United States.

Alberts served as the cancer center’s director from 2005 until his retirement in 2013 and continued his work part-time until 2017.

“Dr. Alberts was a visionary leader with a unique capacity to move forward ambitious academic agendas while consistently relating to and supporting the success of the cancer center team members,” said Clara Curiel-Lewandrowski, co-director of the Skin Cancer Institute, chief of dermatology and director of the Cutaneous Oncology in the University of Arizona Division of Dermatology, Department of Medicine. “The UACC Skin Cancer Institute, co-founded by Alberts in 2007, represents an example of his commitment to addressing relevant challenges affecting our Arizona community through the power of alliance and a team approach driven by scientific rigor. I am grateful for his mentorship.”

Alberts received his Doctor of Medicine in 1966 from the University of Virginia School of Medicine. He completed an internship at the University of Wisconsin, then was a clinical associate in medical oncology at the National Cancer Institute’s Baltimore Cancer Research Center.

Alberts conducted his internal medicine residency at the University of Minnesota. He served on the faculty of the

University of California, San Francisco, for five years and obtained board certification in medicine and medical oncology in 1973.

In 1975, he moved to Arizona with his wife, Heather, and children Sabrina and Timothy. He joined the University’s College of Medicine as an assistant professor where he served for 48 years, retiring as a Regents Professor of Medicine, Pharmacology, Nutritional Science, Public Health and BIO5 at the University’s College of Medicine.



**His compassion, commitment and overall care for his patients was unmatched. He will be remembered by his patients and their families forever.**



— Sabrina Alberts Plattner

“Our dad was always there for his patients at any time of the day or night,” said his daughter Sabrina Alberts Plattner, health educator, senior, in the UArizona Health Promotion Sciences Department of the Mel and Enid Zuckerman College of Public Health. “His compassion, commitment and overall care for his patients was unmatched. He will be remembered by his patients and their families forever.”

Alberts’s life dedication was not only to his career but also to his loving wife of 60 years, Heather, and their family.

“He was an especially proud grandfather to Samuel, Sydney and Tate Alberts and Sophie and Emma Plattner,” Plattner said. “He had a great sense of humor and passion for sports, especially the UArizona basketball and football teams, where he was a season ticket holder for 48 years.”

During his time at the Cancer Center, Alberts pioneered new treatments for advanced ovarian cancers, including in vitro tumor cell chemosensitivity testing for personalized medicine strategies, intraperitoneal chemotherapy, and maintenance chemotherapy. He also assisted in creating a dietary and physical activity intervention for survivors to prevent cancer recurrence.

“Dave was a true visionary in his recognition of the many cancer deaths that could be prevented were we to fully implement the prevention strategies that we already know about,” said Peter Lance, professor emeritus in the UArizona Department of Molecular and Cellular Biology.

Alberts’s laboratory research concentrated on the evaluation of new endpoint biomarkers for cancer prevention trials with a special focus on precursor lesions for bladder, breast, colorectal, cervical, endometrial, ovarian, prostate and skin cancers using quantitative histopathology approaches. His NCI funded drug and diagnostics research resulted in 18 patents and the co-founding of four Arizona pharmaceutical and biotechnology companies.

Alberts was an eternal optimist, according to Jennifer W. Bea, co-director of the cancer center shared resources and co-leader of the Cancer Center’s Cancer Prevention and Control Research Program and associate professor in the Mel and Enid Zuckerman College of Public Health.

“He said to me and to our fellows once in a career development session, ‘I can



Source: University of Arizona Cancer Center

outlast any reviewer.' I never forgot it. It pushes me still," Bea said. "He believed in the quality of our science and patient care and simply persisted until the grants were won and the approvals acquired."

Bea said that as her supervisor and mentor, Alberts gave her increasingly difficult tasks, some of which she felt unprepared.

"He then cheered me on and coached me to the finish line, never criticizing, just supporting. Whenever I feel frustrated with a student, staff member, or colleague, I ask myself, 'What would Dave do,'" Bea said. "I know the answer. He would operate from a place of kindness and collaboration, always moving toward our common goals. Dave was also a connector and a master at putting multidisciplinary teams together and fostering their success."

Bea said that beyond work, he treated everyone like family, and invited them into his home often for program gather-

ings, networking with trainees, celebrations, and more. "Many of us know his wife, Heather, his children, and grandchildren and care deeply for them, as well," Bea said.

During his career, Alberts also served as an advisor to numerous cancer research foundations and committees. He was the chair of the Oncologic Drug Advisory Committee to the FDA from 1984 to 1986 and the National Cancer Institute's Board of Counselors to the Division of Cancer Prevention from 1990 to 1994. He was on the Board of Scientific Advisors from 1999 to 2006 and on the Clinical Translational Advisory Committee from 2006 to 2009.

Alberts authored or co-authored more than 540 peer reviewed publications, 100 book chapters and 60 invited articles, and editor and co-editor of nine books.

He served on the editorial boards of peer-reviewed scientific journals including serving as associate editor for *Cancer*

*Research* from 1989-2002 and co-editor-in-chief of *Cancer Epidemiology, Biomarkers and Prevention* from 2002 and 2008.

In June 2001, was named by the journal, *Science*, to be one of the top three National Institutes of Health-funded clinical researchers in the United States.

Hsiao-Hui (Sherry) Chow, co-director of cancer center shared resources, analytical chemistry, said that Alberts's legacy as a compassionate mentor and a steadfast advocate for excellence will endure in the lives of those he touched.

"Dr. Alberts was a beacon of inspiration and unwavering support to all who had the privilege of crossing paths with him," Chow said. "His unwavering commitment to excellence, coupled with a genuine sense of compassion, shone brightly in every endeavor he undertook."

Chow said Alberts's dedication to his work was matched only by the depth of care he showed for his colleagues and friends.



“Whether it was a word of encouragement during challenging times or a helping hand to navigate professional complexities, he was always there, a reliable source of support and wisdom,” Chow said. “We will carry forward the profound impact of his guidance, ever grateful for the lessons learned from a true exemplar of humanity.”

In 2003, the American Association for Cancer Research (AACR) awarded him the Dr. Joseph H. Burchenal Clinical Research Award, and a year later, the American Society for Preventive Oncology honored him with its Distinguished Career Award for research excellence for his contributions to cancer clinical care and the AACR awarded Alberts with its Cancer Research and Prevention Foundation Award for Excellence in Cancer Prevention Research Worldwide. In 2014, he was honored by the American Association for Cancer Research with its Pioneer in Cancer Prevention Awards.

Cynthia Thomson, interim associate director for Population Science and Cancer Center shared resources, said that Alberts’s generous and selfless investment of time into his colleagues has left a lasting memory for her and for many people who knew him.

“In life, we are sometimes blessed to meet people who alter our life’s course for the better. Dave Alberts was the person for me. I can never repay his kindness, his willingness to impart knowledge, and to share his astute vision,” said Thomson. “He was ahead of his time in seeing the importance of engaging women in cancer prevention science. He worked hard to ensure our voices were heard and our lives were inspired to prevent cancer and ‘save people from the labor of being sick.’”

Alberts’s memorial service was August 6, at 10 a.m. at the Westward Look Resort. The family asks that in lieu of flowers you please make donations to support the Dr. David Alberts Endowed

Fellowship for Cancer Prevention, payable to the University of Arizona Foundation/University of Arizona Cancer Center and mail to 1515 N. Campbell Ave., P.O. Box 245024 Tucson, AZ, 85724-5018.

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**Dave was a true visionary in his recognition of the many cancer deaths that could be prevented were we to fully implement the prevention strategies that we already know about.**



— Peter Lance

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## IN THE ARCHIVES


**CANCER  
HISTORY  
PROJECT**

## In 1971, Chris Lundy had minute odds of survival. He is now the longest living BMT recipient at the Hutch

By Deborah Doroshow and Alexandria Carolan



**Deborah Doroshow, MD, PhD**

Assistant professor of medicine,  
Tisch Cancer Institute,  
Icahn School of Medicine at Mount Sinai

- **Podcast:** [Chris Lundy had one week to live; 52 years later, he is the longest living BMT recipient at the Hutch](#) | Sept. 15, 2023

At 75, Chris Lundy is one of the longest living recipients of a bone marrow transplant.

He was among the patients included in the 1975 paper published in the *New England Journal of Medicine* titled “Bone-Marrow Transplantation.”

“It was a paper everyone interested in bone marrow transplantation read word for word,” Frederick Appelbaum, executive vice president, professor in the Clinical Research Division, and Metcalfe Family/Frederick Appelbaum Endowed Chair in Cancer Research at Fred Hutchinson Cancer Center, wrote in his book “Living Medicine.” “It was the article that introduced marrow transplantation to the general medical community.”

An interview and podcast with Appelbaum about his book “Living Medicine,” is available on the [Cancer History Project](#).

Lundy’s path to diagnosis and treatment was not simple. At age 18, during basic training in Fort Polk, LA, Lundy slipped and broke his wrist.

At the hospital, the doctors set his wrist and ran some blood tests. What Lundy thought would be a simple visit turned into an eight-month stay.

“What they found was that I had an extremely low hematocrit,” Lundy said to Deborah Doroshow, assistant professor of medicine, hematology, and medical oncology at the Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai. “I was jaundiced, I had double walking pneumonia, and I was a pretty sick puppy. And if I hadn’t broken my wrist and gone to the hospital, I probably wouldn’t have been around too much longer—because I think my hematocrit was about four and a half or five, and normal was supposed to be up around 15.”

Doroshow, who is also a historian of medicine, is a member of the editorial board of the Cancer History Project.

Doctors at the hospital in Fort Polk thought Lundy had a reactionary hemolytic anemia, but it took them a while to settle on an initial diagnosis. They conducted several bone marrow biopsies, took blood for testing, and began treating Lundy with prednisone—the hope being that this might jumpstart his red blood cell count. Nothing seemed to work.

“I felt like a big pin cushion,” Lundy said.

After eight months, they transferred him to a hospital in Fort Sam Houston, TX. There, doctors determined that Lundy had paroxysmal nocturnal hemoglobinuria.

“In the medical books, there were literally about four sentences after the name, and that’s about all they had,” he said. “I was, like, the 800th recorded case of someone having this.”

The suspected cause?

In Fort Polk, recruits going through basic training were moved out to the football field and put in tents. The tents were sprayed with insecticide.

“I had been sprayed with insecticide, and the insecticide had stopped me from making blood,” Lundy said.

Lundy spent 38 months in the hospital. During that time, he contracted pneumonia 34 or 35 times.

“You can have a sniffle, and I would get pneumonia,” he said.

Due to his weakened immune system, Lundy wasn’t allowed many visitors, and spent a lot of time on his own.

“Now if someone is in a room, you have some different things that you can entertain yourself with—like radio, tv, etc. I didn’t have any of those things,” he said. “I got a paint-by-number set. I got

a couple of coloring books. I got a couple of paperback books from the cart that went around, but anything that came in the room had to stay in the room.

“And anything that came in the room had to be treated, or radiated before it came into the room so that it didn’t bring bugs with me, or with it.”

In Fort Sam Houston, Lundy’s doctors exhausted his treatment options, recommending that he go to Fred Hutch Cancer Center in Seattle.

“It turned out to be a good thing because that’s where I met Dr. [E. Donnell Thomas, who later was in charge of doing the transplant,” Lundy said. Thomas would share the Nobel Prize in Physiology or Medicine in 1990 for discoveries concerning organ and cell transplantation in the treatment of human disease.

In Seattle, Lundy enrolled in junior college, began living in his own apartment, and continued to have his blood evaluated.

“We did a quick routine that kind of jolted the system, and my system responded, and it started making blood cells again, and things were looking very rosy,” he said.

Lundy’s doctors gave him the OK to embark on a project—he began to build a fiberglass hatch to make an aquarium.

“Two days later, I’m doing this application, within 24 hours, my blood counts plummeted,” he said. “It went like a vertical drop, and I felt terrible...That was the beginning of the worst times, if you will, because I never really recovered from that incident.”

As Lundy’s blood counts dropped, his doctors had been looking at the possibility of a bone marrow transplant. The procedure was new, dangerous, and uncertain.

The following year was marked by frequent hospital stays and illness—at one point running a fever of 106 for about a week. At one point not long before the transplant, Lundy was confined to his hospital bed 24/7.

One day in 1971—five years after Lundy’s initial diagnosis—a doctor came into his hospital room, offering him good news and bad news.

The good news?

“We’ve decided that we’re going to try and do the bone marrow if you want to,” the doctor told Lundy. “The estimate is that you probably only have a 10% chance of pulling through it.”

The bad news? Lundy only had a week to live if he decided not to go through with the bone marrow transplant.

“At that point, the world felt really heavy,” Lundy said.

The doctors HLA-typed Lundy’s family and determined that his brother, Jerry Lundy, was a match. Jerry agreed to be a donor and Chris decided to go through with the transplant.

“I was fine. No graft versus host disease, no hiccups or bumps in the road. I just sailed right through it in terms of all the things they thought could happen, might happen, and none of that did,” he said.

Jerry, however, experienced complications—while doctors and nurses took blood from Jerry, he went into cardiac arrest. The medication they had given him for the procedure, protamine, was determined to be the cause.

“It happened three days in a row, the same thing,” Jerry Lundy said. “First day they shot it all in and I went into cardiac arrest. And then the next day they spread it out over a period of time, and I still went into cardiac arrest. And the

third day they did the same thing, and did it again.”

After the third time, doctors released Jerry Lundy without giving him the coagulant.

“[They] just let me go with my blood thin,” he said. “I couldn’t shave, couldn’t go nowhere. I couldn’t do nothing that I would take a chance on cutting myself, because I would’ve bled out.”

Complications aside—the transplant was a success. In 1972, Lundy returned to school. He went on to have a career as a middle and high school teacher.

“For the most part, I’ve always felt like it was a part of my life,” Lundy said. “Because I was number 29 to have the transplant, it turns out, as the years go by, I am longer-living.”



Chris and Jerry Lundy spoke with Deborah Doroshov. A [podcast](#) and transcript of this conversation is available on the [Cancer History Project](#).

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*This column features the latest posts to the [Cancer History Project](#) by our growing list of [contributors](#).*

*The Cancer History Project is a free, web-based, collaborative resource intended to mark the 50th anniversary of the National Cancer Act and designed to continue in perpetuity. The objective is to assemble a robust*

collection of historical documents and make them freely available.

Access to the Cancer History Project is open to the public at [CancerHistoryProject.com](https://CancerHistoryProject.com). You can also follow us on Twitter at [@CancerHistProj](https://twitter.com/CancerHistProj), or follow our [podcast](#).

Is your institution a contributor to the Cancer History Project? Eligible institutions include cancer centers, advocacy groups, professional societies, pharmaceutical companies, and key organizations in oncology.

To apply to become a contributor, please contact [admin@cancerhistoryproject.com](mailto:admin@cancerhistoryproject.com).

## IN BRIEF



## UK Markey attains Comprehensive designation

The University of Kentucky Markey Cancer Center has attained the NCI Comprehensive Cancer Center designation.

In addition to achieving the highest-level designation, the UK Markey Can-

cer Center was awarded \$13.5 million through a five-year renewal of its NCI Cancer Center Support Grant.

The University of Kentucky's leaders decided to seek the NCI Cancer Center designation in 2009, reaching that goal within 4 years.

"NCI designation in 2013 was an important milestone, but not the final destination. The elevation to Comprehensive Cancer Center is an achievement that underscores our commitment to addressing the health care needs of the people of Kentucky, a state burdened by the highest cancer incidence and death rates in the nation," UK Markey Cancer Center Director B. Mark Evers said in a statement. "As a Comprehensive Cancer Center, we are strengthened in our mission to lead the charge against cancer through groundbreaking research, innovative treatments and outreach efforts to bring vital resources and care to every corner of Kentucky. Together, we will turn the tide against this disease to conquer cancer in the Commonwealth."

Since obtaining the Cancer Center designation in 2013, Markey outpatient visits have increased by 69% and new patient volume by 75%.

In other metrics:

- More than 100 new cancer researchers have been recruited to UK.
- External funding to Markey researchers has more than doubled. Markey researchers currently hold more than \$60.4 million in external funding, more than 70% from the National Institutes of Health, including NCI.
- Markey received nearly \$7 million in additional funding from grants only available to NCI-designated cancer centers.

Markey's clinical growth has necessitated the need for newer patient facilities. In 2021, the University of Kentucky began planning a new outpatient cancer treatment center and advanced ambulatory complex that will bring Markey's outpatient services under one roof. Anticipated to open in 2027, the complex will allow Markey to further grow and expand as more patients from in and out of state need its services.

"Comprehensive status is an investment of faith from the NCI in our work to eradicate cancer in Kentucky," Eric Monday, co-executive vice president for health affairs, said in a statement. "Here at UK, we're fortifying that investment as we begin construction of a new outpatient cancer and ambulatory facility that will house more than 300,000 square feet of cancer-specific services, which will enable us to further increase our capacity to treat and heal even more Kentuckians."

Markey has 250 faculty members from 11 of the UK's 16 colleges.

Markey's clinical and research work is backed by the university, the Commonwealth of Kentucky, and philanthropy through the Markey Cancer Foundation and UK HealthCare Philanthropy.

## AACR forms Cancer Centers Alliance to foster collaboration among cancer center leadership

The American Association for Cancer Research has established the AACR Cancer Centers Alliance to foster collaboration and innovation among cancer centers to advance scientific discoveries.

AACR announced the formation of the alliance at a press briefing for the AACR Cancer Progress Report 2023

Sept. 13 at the National Press Club in Washington, DC.

“AACR, with its convening power and broad multidisciplinary scientific scope, is really uniquely positioned to identify, support, and accelerate scientific priorities that lead to lifesaving discoveries,” Margaret Foti, CEO of AACR, said at the event. “For this reason, numerous cancer center directors have reached out to AACR to serve as a catalyst in support of the center’s need to marshal their resources and collaborate directly, effectively, and synergistically to address the nation’s cancer mission and its many challenges.”

The Cancer Centers Alliance will focus on basic and translational research, clinical research in clinical trials, training and diversity, and speaking with a unified voice, said David Tuveson, Roy J. Zuckerberg Professor of Cancer Research, and cancer center director of Cold Spring Harbor Laboratory.

Tuveson, who spoke at the meeting in a pre-recorded message, is the steering committee chair of the Cancer Centers Alliance.

“Projects within these areas will link our cancer centers closely to each other and to AACR,” Tuveson said. “AACR Cancer Centers Alliance looks forward to working with the White House, the NCI, as well as patients and patient advocacy groups, the biopharma industry regulatory agencies, including the FDA and allied cancer organizations, including the AACI, to meet our new objectives and closing.”

The Alliance steering committee chair and subgroup chairs are:

- David A. Tuveson, Cold Spring Harbor Laboratory Cancer Center (steering committee chair)
- Carlos L. Arteaga, UT Southwestern Simmons Comprehensive Cancer Center (subgroup co-chair: clin-

ical research, clinical trials, and regulatory science and policy)

- John L. Cleveland, Moffitt Cancer Center (subgroup chair: basic and translational research)
- Ruben A. Mesa, Atrium Health Wake Forest Baptist Comprehensive Cancer Center (subgroup chair: education, training, professional advancement, and diversity, equity, and inclusion)
- Louis M. Weiner, Georgetown Lombardi Comprehensive Cancer Center (subgroup co-chair: clinical research, clinical trials, and regulatory science and policy)
- Cheryl L. Willman, Mayo Clinic Comprehensive Cancer Center (subgroup chair: speaking with a unified voice)

An article focused on the Alliance’s initial plans was published in the journal *Cancer Discovery*. A detailed story about the AACR Cancer Centers Alliance will appear in the Sept. 22 issue of *The Cancer Letter*.

## Dana-Farber, Beth Israel Deaconess plan to build free-standing inpatient cancer hospital

Dana-Farber Cancer Institute and Beth Israel Deaconess Medical Center have formed a comprehensive collaboration designed to advance cancer care and build the region’s only independent, free-standing inpatient hospital for adult cancer patients.

The collaboration is designed to improve the future patient experience by improving access, by better integrating innovations at the bedside, and by offering high-value care.

The collaboration focuses exclusively on cancer care.

While each organization will remain fully independent—including executive leadership, boards of trustees and philanthropy—the Dana-Farber Beth Israel Deaconess Cancer Collaboration leverages the expertise of both institutions.

The proposed inpatient cancer hospital will operate under the license of Dana-Farber and provide adult medical oncology care.

Together, Dana-Farber and BIDMC, with its affiliated physician group, Harvard Medical Faculty Physicians, will establish a coordinated clinical and organizational structure for oncology care in the Longwood Medical Area of Boston.

The hospital will increase adult patient capacity. It will also create flexibility to incorporate the innovations and technology in cancer care that Dana-Farber’s and BIDMC’s researchers and clinicians are developing every day. Located adjacent to existing Dana-Farber and BIDMC facilities in Longwood, the proposed cancer hospital will support both seamless patient care and continued focus on research initiatives.

“Cancer care has changed dramatically. Through this collaboration, our patients and their loved ones will benefit tremendously from Dana-Farber’s leading-edge scientific discovery and exceptional patient care. We believe this will position us to provide world renowned cancer treatment in outpatient and inpatient settings well into the future,” Laurie H. Glimcher, president and CEO of Dana-Farber, said in a statement. “Beth Israel Deaconess Medical Center and the physicians of HMFP share our vision and are equally committed to ensuring a superior patient experience and advancing a collaborative focus on world-class cancer care and research that will benefit our region and the world.”

Pending regulatory approvals, it will take several years to implement the cancer collaboration and construct the new cancer hospital. Dana-Farber's current affiliation with Brigham and Women's Hospital for inpatient and surgical care, long-renowned for its positive outcomes and high-quality patient care, will continue through the transition.

BIDMC's independent oncology programs will also continue until the collaboration is in place.

Outpatient oncology care at Dana-Farber's existing locations in Boston, Chestnut Hill, and other regional campuses will not be interrupted.

Likewise, the cancer institute's partnership for pediatric cancer care with Boston Children's Hospital will not change.

Beth Israel Lahey Health will also continue to invest in advancing cancer services at BIDMC and at its other hospitals, fulfilling their commitment to provide access to extraordinary care in community settings.

"Together, we are taking bold steps to transform how we care for individuals and families touched by cancer, expand equitable access to life-changing care, and harness the power of scientific discovery," Kevin Tabb, president and CEO of Beth Israel Lahey Health, said in a statement. "This collaboration and a dedicated, free-standing cancer hospital will be truly unique in Massachusetts. Our community needs and deserves both."

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## City of Hope receives \$100M gift from Panda Express founders to create national integrative oncology program

City of Hope received a \$100 million gift from Andrew and Peggy Cherng, philanthropists, co-founders and co-CEOs of Panda Express, to create a first-of-its-kind, national integrative oncology program that brings together Eastern and Western medicine to improve outcomes and quality of life for cancer patients and survivors.

The gift, which will establish the Cherng Family Center for Integrative Oncology at City of Hope, is the largest single philanthropic contribution for cancer care in City of Hope history and the largest donation the Panda Charitable Family Foundation has made to any organization.

Integrative oncology is a whole-person approach to cancer care that draws from diverse cultures, particularly traditional Chinese medicine and other Eastern healing traditions. Research on Eastern therapies could result in evidence-based insights that fuel the development of more effective cancer medicines and care.

An estimated 40% of cancer patients use integrative therapies annually to address disease and chronic issues, such as pain. Studies show integrative therapies can support better health, improved quality of life and optimal clinical outcomes.

However, few health care organizations—let alone cancer centers—provide access to integrative therapies under physician supervision, much less use them holistically in treatment for patients with cancer.

City of Hope will make integrative oncology an evidence-based, interwoven standard of care that supports optimal cancer treatment and survivorship.

"We are grateful for this gift, which will allow us to lead the way in integrative oncology and continue to pioneer compassionate medical innovation as

we have done at City of Hope for more than 100 years," Robert Stone, CEO of City of Hope and the Helen and Morgan Chu Chief Executive Officer Distinguished Chair, said in a statement. "Innovative and holistic care is part of our culture and mission; we are committed to supporting and treating the whole patient—not just the cancer. I am honored that our cancer expertise, world-class research environment, national patient population, robust clinical trials program, and compassionate ethos have prepared City of Hope to lead this work."

Beginning in Southern California and eventually spanning the City of Hope national system, the Cherng Family Center's work will be led by Richard T. Lee, Cherng Family Director's Chair for the Center for Integrative Oncology at City of Hope and an integrative oncology expert. City of Hope has more than 15 years of leadership in supportive care medicine with researchers who continue to bring forth new, evidence-based standards for preventing and managing the adverse effects of cancer and its treatment.

The Cherng Family Center for Integrative Oncology will pursue the following goals:

- City of Hope will accelerate research, therapy development, and clinical trials so scientists and physicians can develop evidence-based practices for cancer patients nationwide.
- Education and training programs will address the shortage of knowledgeable clinicians in this field. Within the next year, City of Hope plans to create one of the first integrative oncology fellowships created and led by oncologists.
- Programs will be piloted at City of Hope campuses in Los Angeles and Orange County, CA. Experts

will build scalable infrastructure and develop platforms to track clinical data to further scientific discovery and improve cancer patient outcomes. The benefits of integrative oncology will then be extended to patients throughout City of Hope's national cancer care and research system.

"Panda Restaurant Group began 50 years ago with a vision to bring the best of Eastern and Western flavors and cultures together through food. In the same spirit, we hope the Cherng Family Center of Integrative Oncology becomes a model of bringing the best of Eastern and Western medicine together to unlock holistic healing for our communities," Peggy Cherng said in a statement. "At Panda, one of our core values is giving and we are grateful to help establish, through this gift from the Panda Charitable Family Foundation, pioneering integrated cancer care to not only save lives, but improve the quality of life for cancer patients."

The Panda Charitable Family Foundation has supported City of Hope for many years, providing funding to study natural therapies as well as corporate sponsorships and donations.

"The Cherng Family Center for Integrative Oncology will be the epicenter of translational research, new drug development and holistic care that meets a pressing need for patients and enhances our connection to the diverse communities we serve," Edward S. Kim, vice physician-in-chief of City of Hope National Medical Center, said in a statement. "City of Hope is creating a new standard of care through a scientifically rigorous process. Our vision is to create an international destination for integrative oncology that transforms the way people with cancer receive care."

## AACI publishes report on staff retention at clinical trials offices

The AACI CTO Staff Retention Task Force published a report that highlights key data from two surveys distributed to cancer center directors in March 2022 and again in March 2023.

The report also outlines successful staff retention strategies implemented by AACI cancer centers.

Led by Leonidas C. Platanius, director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University, the AACI Clinical Trials Office Staff Retention Task Force was established in response to the mass resignation of CTO staff amid the COVID-19 pandemic.

Colleagues from 16 AACI member cancer centers have participated in discussions about ongoing workforce challenges, identifying efforts to reduce turnover and retain staff, minimize impact on clinical trial operations, and work with NCI and industry partners on these issues.

Based on the most common reasons CTO staff cited for leaving their cancer centers, the task force formulated recommendations to help guide the centers in improving staff retention and recruitment, both immediately and in the long term.

The recommendations were shared with AACI members in the September 2022 *AACI Commentary*.

## KU establishes four-state Heartland Consortium as part of All of Us Research Program

The University of Kansas Medical Center is establishing a Midwest consortium as part of the National Institutes of Health's All of Us Research Program. KU Medical Center and its partners will receive \$6.3 million in initial funding, with the potential to renew the award every year for four years.

The Heartland Consortium includes academic medical centers at the University of Kansas, the University of Iowa, the University of Missouri, and the University of Nebraska.

The goal of the All of Us Research Program is to advance precision medicine research, one day enabling clinicians to tailor patient care by accounting for individual differences in biology, behavior, and environment.

To that end, the program has created a national research resource that will include comprehensive de-identified health information from more than 1 million people in the U.S.

A network of consortia made up of health care provider organizations helps enroll participants who reflect the diversity of the U.S., but this is the first consortium dedicated to engaging participants in the Midwest. Together, the Heartland Consortium seeks to enroll more than 6,000 participants in its first year.

The consortium aims to reach out to a wide variety of participants, with special emphasis on those in rural areas, as well as other groups historically underrepresented in research.

"The Heartland Consortium is excited that our region will now be a part of the national All of Us Research Program, helping to further precision medicine research by ensuring people in Kansas, Missouri, Nebraska and Iowa are represented," Akinlolu Ojo, consortium principal investigator and executive dean of



the University of Kansas School of Medicine, said in a statement. “Our participation was made possible by the substantial resources and researcher expertise from disciplines across the KU schools of Health Professions, Medicine and Nursing, and from other consortium members from our four-state region.”

Unlike research studies that focus on one disease or group of people, All of Us is building a diverse and secure database that can inform thousands of studies on a variety of health conditions.

Researchers will be able to tap into a broad database to better understand the risk factors for certain diseases and inform future treatments and prevention.

All of Us follows all federal, state, and local laws in keeping data safe. The program removes all personal details from the data to prevent participants from being identified.

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## **Fred Hutchinson granted \$38.7M to serve as national coordinating center for Asian American, Native Hawaiian & Pacific Islander health studies**

Fred Hutchinson Cancer Center will be the national coordinating center for a new epidemiological cohort study among Asian Americans, Native Hawaiians and Pacific Islanders.

Fred Hutch was awarded a seven-year, \$38.7 million National Institutes of Health grant to coordinate the effort to gather important health information on these populations, which are underrepresented in biomedical research.

The study is funded by the National Heart, Lung, and Blood Institute, along with four other NIH institutes. Researchers at the University of Hawaii, Stanford Medicine, University of Chicago, Fox Chase Cancer Center, Temple Health, and NYU Langone Health’s Perlmutter Cancer Center will lead community-engaged efforts to recruit and follow individuals from AsA-NHPI populations residing in their geographic areas.

Garnet Anderson, senior vice president and director of Fred Hutch’s Public Health Sciences Division will lead the study’s coordinating center.

Anderson is also a principal investigator for the Women’s Health Initiative Clinical Coordinating Center at Fred Hutch and holds the Fred Hutch 40th Anniversary Endowed Chair.

“There are a lot of gaps in our knowledge about the health of these populations and their risk factors for a variety of diseases,” Anderson said in a statement. “We are recognizing and responding to the lack of data for these populations.”

The coordinating center leadership team includes:

- James Floyd, cardiovascular epidemiologist and associate professor of medicine at the University of Washington School of Medicine.
- Kwun Chuen (Gary) Chan, professor in the University of Washington Department of Biostatistics and Department of Health Systems and Population Health and associate director of the National Alzheimer’s Coordinating Center.
- Robert Kaplan, professor in the Department of Epidemiology & Population Health and the Dorothy and William Manealoff Foundation and Molly Rosen Chair in Social Medicine at the Albert Einstein College of Medicine.

Kaplan, a frequent collaborator with investigators at Fred Hutch, provides expertise gained from his leadership of the Hispanic Community Health Study/Study of Latinos, or HCHS-SOL, a similar study in the Hispanic/Latino population.

The study will drill down into risk factors that drive cardiovascular disease, metabolic disorders, mental health, and other chronic health conditions, collecting a number of biospecimens including blood, urine, and microbiome samples to analyze for this and future studies.

“The goal is to recruit at least 10,000 people, which isn’t big enough to do genomics studies, but it will be a contribution to genetic consortiums,” Anderson said. “In addition to describing the health status of these populations currently, we’ll collect data and biospecimens that can be shared and follow these individuals over time to monitor their health. Studies like this generate resources and draw in people and ideas. They support a lot of novel research in the population sciences.”

Principal investigators for the study include:

- University of Hawaii: Marjorie Mau, Alika Maunakea, and Lani Park
- Stanford Medicine: Ann Hsing, Clete Kushida, Paul Wang, and Joseph Wu
- University of Chicago: Bri-sa Aschebrook-Kilfoy
- Fox Chase Cancer Center and Temple Health: Carolyn Fang and Grace Ma, of the Lewis Katz School of Medicine at Temple University, and Frank Hu of Harvard University
- NYU Langone Health’s Perlmutter Cancer Center: Jiyoung Ahn and Yu Chen

## Emory Winship receives \$24.8M from ARPA-H for mRNA therapeutics project

Winship Cancer Institute of Emory University received a three-year, \$24.8 million cooperative agreement from the Advanced Research Projects Agency for Health to lead the CUREIT program: “Curing the Uncurable via RNA-Encoded Immunogene Tuning.”

The CUREIT project aims to develop generalizable mRNA platforms that can be harnessed to train the immune system to more effectively fight cancer and other diseases.

The ARPA-H funding supports work led by Winship member Philip Santangelo, a professor in the Wallace H. Coulter Department of Biomedical Engineering at Emory and Georgia Institute of Technology.

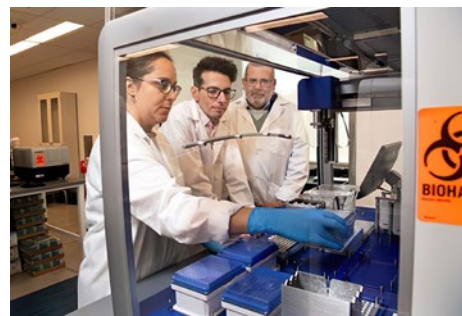
CUREIT is the third cancer-related ARPA-H initiative, along with the Precision Surgical Interventions program and the ARPA-H Biomedical Data Fabric Toolbox project.

CUREIT is the first award from the ARPA-H Open Broad Agency Announcement, which seeks transformative ideas for health research breakthroughs and technological advancements.

The application period is open until March 2024 and future projects will be funded on a rolling basis.

“It’s a tremendous honor for Emory to be the inaugural recipient of this very first ARPA-H Open BAA award, which will elevate and invigorate the visionary, life-changing health care research of our faculty,” Emory President Gregory L. Fenves said in a statement.

Many incurable, debilitating diseases, including certain types of cancer, lupus, and some viral and bacterial infections, are caused or exacerbated by dysregulation of the immune system, which impairs the body’s ability to control the immune response and leaves a patient vulnerable to the disease. Immune modulation is a way to enhance the body’s immune response. The conventional methods of immune modulation—vaccines, antibodies, small molecules, and cell-based therapies—face manufacturing complexities and limitations in their ability to engage immunity.



The Santangelo Lab will approach this challenge by developing a novel class of mRNA-based drugs to precisely “turn on or turn off” genes in individual immune cells.

“By combining mRNA-encoded antigens with gene modulation technology, we will be able to radically enhance specific immune responses,” Santangelo said in a statement. “This technology, which operates transiently without modifying DNA, can offer a potential breakthrough in treating cancers, autoimmune disorders and infectious diseases.”

The research plan unfolds through two parallel pathways. In the first, mRNA-based drugs will directly target immune cells within the body, triggering the expression of critical target proteins and meticulously modulating gene activity for improved immune function. The second approach employs a

streamlined, fully functional cell-based therapy, combining messenger RNA-expressed antigens and gene modulators outside the body to prevent and treat diseases. These pathways, adaptable to diverse disease types, will be employed independently or in tandem to elevate vaccines and standard treatments.

Rafi Ahmed, co-leader of Winship’s Cancer Immunology Research Program, will lead the studies focusing on strategies for overcoming T-cell exhaustion, which may have significant implications for treating cancer in the future.

“With many cancers and chronic infections, the T-cells become dysfunctional, which we refer to as T-cell exhaustion,” Ahmed said in a statement. “If we can be successful at reversing T-cell exhaustion, this could have very broad applications to all cancers.”

One goal for the research team is to enhance T cell function using Santangelo’s system, which involves utilizing the mRNA platform to turn on and turn off RNA inhibitors to help modulate the cells of the immune system.

Iñaki Sanz, also a member of Winship’s Cancer Immunology Research Program, will lead the research studies focused on autoimmunity.

“Both cancer and autoimmunity are regulated by abnormal immune responses,” Sanz said in a statement. “In cancer, a deficient immune response allows or even promotes tumor progression. Whereas, in autoimmunity, an exaggerated, dysregulated immune response is responsible for the disease. Interestingly, cancer immunotherapy is mediated by an autoimmune-like response against the tumor antigens and may in many cases trigger undesired autoimmune reactions. The ability to induce targeted fine regulation of different aspects of the immune response

would enhance efficacy and reduce toxicity of cancer immunotherapy.”

Established in 2022, ARPA-H is a federal agency that supports the development of high-impact research to drive biomedical and health breakthroughs.

“We are grateful to have been selected to be a part of this historic health initiative. We look forward to collaborating with researchers across multiple departments, specialties, and organizations on these pivotal studies, facilitating medical advancements that could potentially enhance lives of countless people nationally and even worldwide,” Suresh S. Ramalingam, Winship’s executive director and Roberto C. Goizueta Chair for Cancer Research in Emory University’s School of Medicine, said in a statement.

## Winship’s Suresh Ramalingam receives IASLC award for contributions to thoracic cancer research



Suresh Ramalingam, executive director of Winship Cancer Institute of Emory University, was awarded the Paul

A. Bunn, Jr. Scientific Award Sept. 9 at the 2023 IASLC World Conference on Lung Cancer.

Presented by the International Association for the Study of Lung Cancer, The Paul A. Bunn, Jr. Scientific Award recognizes an IASLC scientist for a lifetime achievement of scientific contributions to thoracic cancer research. Bunn’s studies set worldwide standards for the treatment of lung cancer and identified issues of natural history and biomarkers of prognosis and therapy selection.

Ramalingam is also a professor and the Roberto C. Goizueta Chair for Cancer Research at the Emory University School of Medicine.

Ramalingam’s research is focused on the development of novel treatment approaches for patients with lung cancer.

Specifically, his group has developed novel treatment options for patients with lung cancer harboring an EGFR mutation, resulting in FDA approval of third-generation inhibitors for metastatic NSCLC.

He leads clinical and translational investigations of novel immunotherapy approaches for the treatment of lung cancer.

Additionally, Ramalingam is the principal investigator for the Emory University Lung Cancer SPORE award from NCI. He is deputy chair for Therapeutics Programs at ECOG-ACRIN, is a former chair of the ECOG-ACRIN Thoracic Malignancies Committee, and is currently the editor-in-chief of *Cancer*.

## Ajay K. Nooka named associate director for clinical research at Winship



Hematologist-oncologist Ajay K. Nooka was named associate director for clinical research at Winship Cancer Institute of Emory University.

In the role, Nooka will provide strategic oversight for all clinical research conducted at Winship, with a focus on supporting high-quality, safe, and ethical research and ensuring that patients have equitable access to Winship’s innovative clinical trials.

Nooka succeeds Edmund K. Waller, who has served as interim associate director for clinical research since February 2022.

Nooka is a professor of hematology and medical oncology and director of the Myeloma Program at Emory University School of Medicine.

He is a member of Winship’s Cancer Prevention and Control Research Program and scientific director of the Winship Data and Technology Applications Shared Resource.

As the principal investigator for more than 40 clinical trials in multiple myeloma, Nooka contributed to the approval of drugs and treatment strategies that are leading to better outcomes. His research interests include genomic and clinical data integration and interpretation; evaluating novel therapeutic

strategies to improve outcomes; and cancer epidemiology.

Nooka is a section editor for the journal *Cancer* and associate editor for the journal *Clinical Lymphoma, Myeloma and Leukemia*.

## Michael J. Zelefsky named director of brachytherapy, vice chair for academic and faculty affairs at NYU



Michael J. Zelefsky is joining NYU Langone's Perlmutter Cancer Center as director of brachytherapy and vice chair for academic and faculty affairs in NYU Grossman School of Medicine's Department of Radiation Oncology.

Zelefsky was also named professor in the Department of Radiation Oncology and leader of the Genitourinary Cancer Disease Management Group. He comes to NYU Langone from Memorial Sloan-Kettering Cancer Center.

An expert on prostate cancer treatment, Zelefsky has made major contributions to the field, shaping clinical practice guidelines and influencing treatment protocols worldwide. He was instrumental in the development of inten-

sity-modulated radiotherapy for the treatment of prostate cancer, which is now employed routinely throughout the world. He is also a renowned opinion leader in the area of stereotactic body radiotherapy for prostate cancer and well as the type of internal radiotherapy known as brachytherapy.

He will work closely with Perlmutter Cancer Center's urologic and medical oncology teams to create a sophisticated, multidisciplinary approach to all aspects of diagnosis, treatment, and side effect management.

"I'm not simply continuing what I've been doing, but going to the next level at NYU Langone, and incorporating the expertise that can be found here," Zelefsky said in a statement. "We want to personalize the treatments for our patients, and best select the optimal therapy based on biologic and genomic markers, as well as quality-of-life variables. There's a strong and innovative imaging department here, which will allow us to use MRI and sophisticated PET scanning to guide treatments, as well as outstanding urology and medical oncology departments, to provide the most comprehensive and multidisciplinary treatment recommendations."

Zelefsky has built one of the largest brachytherapy services in the world and plans to further develop such programs in the Department of Radiation Oncology and Perlmutter Cancer Center.

## Navid Hafez named director of precision medicine and thoracic oncology at the Angeles Clinic

Hematologist-oncologist Navid Hafez was named director of precision medicine and thoracic oncology at the An-

geles Clinic and Research Institute, an affiliate of Cedars-Sinai Cancer.



Hafez will focus on clinical research programs to develop molecular and targeted therapies to treat cancers of the chest cavity, including lung cancers. He also will provide care for patients with thoracic cancer.

"We are pleased to welcome Dr. Hafez to The Angeles Clinic and Cedars-Sinai Cancer," Omid Hamid, chief of translational research and immuno-oncology at The Angeles Clinic and Research Institute and medical director of the Cutaneous Malignancies Disease Research Group at Cedars-Sinai Cancer, said in a statement. "He employs innovative, biomarker-driven targeted and immune therapies to provide top-notch care to patients, and his work to advance the science of precision medicine through clinical trials will benefit patients beyond our institutions."

Hafez said he was motivated to join the field of thoracic oncology by the science, the team approach to research and patient care, and the opportunity to care for patients.

"I enjoy working with patients across a range of life experiences, and that is readily seen in thoracic cancers, which can affect anyone," Hafez said in a statement. "Thoracic cancers, like the patients they affect, are also diverse."

Some require biomarker-driven molecular therapies, some benefit from immune-centered therapies, and some require a combination, and this gives us the opportunity to evaluate novel therapeutic strategies.”

Hafez comes to The Angeles Clinic from Yale School of Medicine where, as assistant professor in the Department of Medicine (Medical Oncology), he contributed to the growth of the Early Therapeutics Division of the Section of Medical Oncology.

He has been named principal investigator of several national studies in the NCI’s Experimental Therapeutics Clinical Trials Network.

“Dr. Hafez’s expertise in precision medicine and thoracic oncology, both as a clinician and researcher, is a tremendous asset,” Karen Reckamp, associate director of clinical research at Cedars-Sinai Cancer. “We look forward to collaborating with him in evaluating novel therapeutic strategies that can bring new, more effective treatment options to patients with thoracic cancers.”

Hafez also works to address diversity, equity, and inclusion in clinical trials and said he is committed to expanding access to leading-edge therapies to underrepresented populations.

“The breakthroughs we make at The Angeles Clinic and Research Institute will improve outcomes for patients of all backgrounds and nationalities—here in the U.S. and around the world,” he said.

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## Mehran Habibi named director of breast surgery for Northwell’s Staten Island University Hospital



Mehran Habibi was named director of breast surgery for Staten Island University Hospital and chief of breast surgery for Northwell Health system’s Western Region, which includes Staten Island, Manhattan, and Westchester County. He will also serve as director of international program development for the Northwell Cancer Institute.

In his role at SIUH, Habibi will be overseeing the Florina Rusi Marke Comprehensive Breast Center, where he will help determine patient risk factors in order to make informed health decisions—using genetic testing, if needed—and provide a wide variety of treatments for breast cancer.

He will also lead multispecialty teams within the region to offer personalized care with advanced screening and innovative surgical, reconstructive, and therapeutic modalities to a diverse patient population.

Previously, Habibi was the founding director of the Breast Center at the John Hopkins University Bayview Campus. With an extensive background in surgical breast oncology, Habibi’s expertise encompasses oncoplastic and nipple sparing mastectomies, risk-reducing mastectomies, rare tumors, and benign diseases. While there, he was credited with the creation of a breast cancer navigation system for patients, multidisciplinary

clinical care, and advancements in imaging localization for breast surgery.

During his time at John Hopkins, he collaborated with the engineering department on high-throughput organoid cultures using droplet microtechnology, significantly enhancing the understanding of tumor progression and drug responsiveness.

Academically, Habibi is deeply committed to increasing research efforts of tumor genomics, the role of microbiome in breast cancer and the application of image analysis.

He is also focused on machine learning within breast cancer management. These areas of research have the potential to aid in the design of personalized cancer treatments and to decrease disparities in cancer care, aligning with Northwell’s strategic mission.

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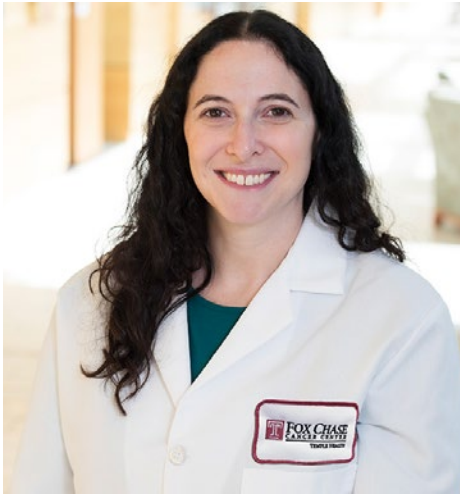
## Avi Srivastava named assistant professor at Wistar



Avi Srivastava was named assistant professor in the Gene Expression and Regulation Program at the Ellen and Ronald Caplan Cancer Center at The Wistar Institute.

A computational biologist, Srivastava brings expertise in advanced computational methods that can be used to establish powerful predictive research tools in cancer biology.

## Sara Small named assistant professor at Fox Chase



Sara Small was named assistant professor in the Department of Bone Marrow Transplant and Cellular Therapies at Fox Chase Cancer Center.

Most recently, Small was a fellow in hematology/oncology in the Department of Medicine at Northwestern Memorial Hospital in Chicago, where she also completed a residency in internal medicine and received the Residency Excellence in Teaching Award.

Small's research seeks to understand how modulation of inflammatory signaling pathways can be leveraged to develop novel treatments that overcome chemotherapy resistance in leukemia.

As a predoctoral fellow in Penn's Cancer Biology Department, Small studied proteins secreted by cells in response to stress and how this contributes to cell senescence, cancer, and aging. Her work was recognized with an NIH Individual

NRSA MD/PhD Fellowship granted by the National Institute on Aging.

She is also the recipient of the American Society of Hematology Research Training Award for Fellows grant and recently received the Hematology/Oncology Fellowship Teaching Award from Northwestern Memorial Hospital.

## Amelie Ramirez Wins AACI Cancer Health Equity Award



Amelie Ramirez, chair of the Department of Population Health Sciences and leader of Salud America! at UT Health San Antonio, won the 2023 Association of American Cancer Institutes Cancer Health Equity Award.

The award recognizes exceptional leadership in promoting health equity, mitigating cancer disparities, and advocating for diversity and inclusion at a cancer center.

Ramirez, nominated by the award by former Mays Cancer Center Director Ruben Mesa, will be recognized at AACI's annual meeting Oct. 2.

For more than 30 years, Ramirez has designed, implemented, and evaluated research and communication mod-

els to reduce cancer and improve Latino health locally and nationally.

She directs the Salud America! national multimedia program to empower its vast network of over 500,000 community and school leaders to drive healthy policy and system changes to promote health equity and support for Latino families.

"I am humbled to receive the AACI Cancer Health Equity Award. It recognizes the hard work we do at the Mays Cancer Center at UT Health San Antonio to promote health equity, study new approaches to reduce health disparities, and improve cancer care for the people in our community and beyond," Ramirez said in a statement.

## Jonathan Licht and Keith McCrae to lead new Blood specialty journals

Jonathan Licht and Keith McCrae were selected by The American Society of Hematology to serve as the inaugural editors-in-chief of the newest additions to the *Blood Journals* portfolio: *Blood Neoplasia* and *Blood Vessels, Thrombosis & Hemostasis*, or *Blood VTH*.

They were selected by the ASH executive committee after a competitive international search.

*Blood Neoplasia* and *Blood VTH* will be peer-reviewed, open access journals that publish original research in specialized blood disease areas. *Blood Neoplasia* will publish research focused on hematologic malignancies and associated disorders, including leukemia, lymphoma, multiple myeloma, and more. *Blood VTH* will focus on thrombosis, hemostasis, and vascular biology, as well as associated disorders, including hemorrhagic disorders and blood platelet disorders.

These new journals complement ASH's existing publications, *Blood* and *Blood Advances*, to meet the demands of the growing field of hematology and aim to foster community in these areas of research.



Licht, director of the University of Florida Health Cancer Center in Gainesville, FL, will be the editor-in-chief of *Blood Neoplasia*. McCrae, director of classical hematology at Cleveland Clinic Taussig Cancer Institute in Cleveland, Ohio, will be the editor-in-chief of *Blood VTH*.

"We're excited to expand ASH's portfolio of journals and delighted that Drs. Licht and McCrae will bring their considerable experience, expertise, and creative vision to the Blood Journals family," Robert Brodsky, ASH president, said in a statement. "*Blood* and *Blood Advances* have well-earned reputations for publishing high-quality hematology research, a tradition we plan to continue with *Blood Neoplasia* and *Blood VTH*."

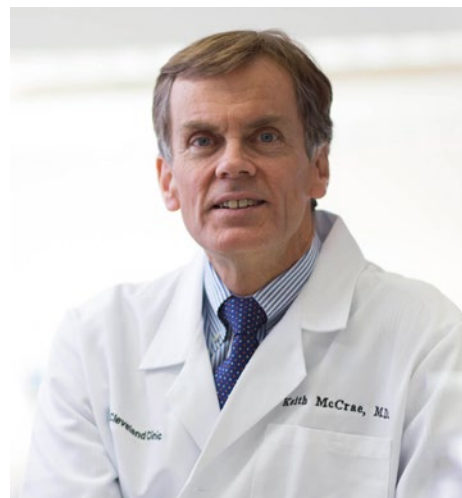
These journals will serve as dedicated forums to advance research and accelerate the exchange of ideas and insights in support of ASH's mission to conquer blood diseases worldwide."

Licht is a physician-scientist with an interest in epigenetic deregulation in blood malignancies. In June 2023, under his leadership, the University of Flor-

ida became the 72nd NCI-designated cancer center.

Previously, Licht was chief of hematology/oncology at Northwestern University and Mount Sinai. He has been an ASH councilor and a co-director of the ASH/European Hematology Association Translational Training in Hematology program.

"I look forward to serving as editor-in-chief of *Blood Neoplasia* and showcasing high-quality, rigorous research in the malignant hematology space," Licht said in a statement. "I've worn many hats throughout my career as both a researcher and a practicing oncologist, which is why I aim to publish exciting, clinically relevant new research in *Blood Neoplasia*."



McCrae is a physician-scientist who also holds appointments in Cleveland Clinic's Department of Cardiovascular and Metabolic Sciences, Lerner Research Institute, Department of Vascular Medicine, Heart and Vascular Institute, and Department of Immunotherapy and Precision Oncology. McCrae was previously on the editorial board of *Blood*.

"*Blood VTH* provides a new venue for hematologists engaged in clinical care and research in thrombosis and hemostasis to bring forward top quality clinical, translational, and basic science to the *Blood* journals," McCrae said in a

statement. "I have been an active clinician and researcher for many years and have seen exciting progress in research in these areas. I hope to use this opportunity as editor-in-chief of *Blood VTH* to build a community for clinicians and researchers in this space within ASH."

Both *Blood VTH* and *Blood Neoplasia* will open for submissions later this month. The first articles will be published online in early 2024 and continuously thereafter.

## Eric Kmiec named editor in chief of *Gene and Genome Editing*



Eric Kmiec, executive director and chief scientific officer of ChristianaCare's Gene Editing Institute, has been selected as editor-in-chief of the scientific journal *Gene and Genome Editing*. Kmiec previously served three years on the journal's board.

"This leading journal in the field has created an environment where gene editing research can undergo rigorous review and provide the field with cutting-edge findings that benefit all," Kmiec said in a statement. "We have a unique opportunity to fill a void in the field by focusing on clear messages about the foundational aspects of

gene editing and accepting papers that cover groundbreaking gene editing discoveries.”

Kmiec is the founder and executive director of the ChristianaCare Gene Editing Institute. He is also the chief executive officer and scientific founder of CorriXR Therapeutics. He is widely recognized for his pioneering work in the fields of molecular medicine and gene editing.

Throughout his professional career, Kmiec has led research teams in developing gene editing technologies and genetic therapies for inherited disorders and cancer. His research has helped elucidate the regulatory circuitry that controls the gene editing of human cells.

Current clinical research centers on developing CRISPR-based gene editing approaches for solid tumors. Squamous cell carcinoma of the lung and esophageal cancer are the lead protocols now advancing through the FDA approval process.

“I will encourage papers from scientists early in their career, and I hope to see scientists with strong voices publishing papers on the important molecular or biochemical aspects of the gene editing reaction,” Kmiec said. “I’d like to see the journal become the go-to publication not only for exciting therapeutic applications but, perhaps more importantly, for the foundational signs that will guide successful implementation.”

*Gene and Genome Editing* currently publishes methodological and translational research covering the spectrum of gene editing techniques and applications in any living organism. Its focus is on translational research with potential short- or long-term impact.

“I am delighted with Eric’s appointment and the plans he has to take the journal in a new direction,” Susanne Steinginga, executive publisher of *Gene and Genome*

*Editing*, said in a statement. “Eric comes with a wealth of knowledge, and every time I speak with him, I’m thrilled to realize how similar our goals and ambitions are for the journal.”

## MUSC Hollings head and neck team awarded \$3.5M to reduce delays in care

A multidisciplinary team at MUSC Hollings Cancer Center, led by Evan Graboyes, was awarded a \$3.5 million grant to test an approach for reducing delays in care for head and neck cancer patients.

Delays in starting radiation therapy after surgery are associated with worse outcomes—and yet half of patients across the country don’t start radiation therapy when they should. The team has spent the last five years studying means to shorten these delays.

Called ENDURE, for Enhanced Navigation for Disparities and Untimely Radiation therapy, the team’s proposed approach addresses the issue at three levels: organization, team, and patient.

Graboyes has been running a 150-patient pilot randomized clinical trial evaluating whether an enhanced patient navigation system can reduce delays starting radiation therapy for patients with head and neck cancers who have surgery at MUSC Health.

Although the final results of that trial likely won’t be ready for publication until early next year, the preliminary data were promising enough for the NCI to fund a multisite trial of ENDURE to confirm these promising findings. This trial will evaluate the ENDURE intervention at Hollings, Siteman Cancer Center at Barnes-Jewish Hospital and Washington University School of Medicine, Duke

Cancer Institute and the Michael E. DeBakey VA Medical Center, in partnership with the Baylor College of Medicine.

“Patient navigation was appealing because it helps improve cancer care for everyone,” Graboyes, a head and neck cancer surgeon who is also director of the Survivorship and Cancer Outcomes Research Initiative at Hollings, said in a statement. “In addition, it’s especially helpful in overcoming barriers to care that disproportionately burden medically vulnerable populations.”

Racial and ethnic minorities, people in rural areas, underinsured patients, and those without a robust support system are all vulnerable to delays in care, he said.

Head and neck cancer care involves multiple teams of clinicians, including surgical, radiation, and medical oncology teams, as well as dental, oral surgery, pathology, and more. Frequently, these teams cross health system lines. In South Carolina, for example, patients may come to Hollings for surgery but receive radiation or chemotherapy at another facility closer to home.

“So it’s a huge team of teams that needs to be coordinated,” Graboyes said. “And the question is, ‘Who is coordinating this team?’ And the answer currently is no one, and that’s why things are going the way they’re going.”

The ongoing clinical trial at Hollings used ENDURE, an enhanced patient navigation system, to help patients to overcome barriers to care, like lack of transportation, and to coordinate with the medical teams.

For the ENDURE trial, each of the sites will be trained in implementing specific processes—for example, implementing referral tracking to make sure that patients continue on the correct treatment path if they are seen at multiple sites.



Clinician discussions about expectations for radiation will be standardized.

In the pilot trial, for example, 74% of patients had a consultation with radiation oncology before they even had surgery, compared with only 31% of patients treated with current standard of care. Importantly, ENDURE also requires three one-on-one sessions between the patient navigator and the patient at critical junctures—before surgery, when being discharged from the hospital, and at the first clinic visit after surgery.

Although the structure of ENDURE will be the same at each institution, each site has flexibility to decide who will do the work. The institution could hire a new patient navigator or could redirect an existing employee to implement the ENDURE method.

“One of the strategies to optimizing fit is to allow some adaptation to local context,” Graboyes said. “I think each site will work out over time what’s best for their local practice in a way that’s intended to be sustainable.”

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## UCLA researchers awarded \$2.5M from DoD to develop brain cancer treatment

A multidisciplinary team of investigators from the UCLA Jonsson Comprehensive Cancer Center was awarded a \$2.5 million Translational Team Science Award from the Department of Defense to develop a tailored treatment for glioblastoma, a deadly brain tumor with limited treatment options.

The team—including David Nathanson, associate professor of molecular and medical pharmacology at the David Geffen School of Medicine at UCLA, Benjamin Ellingson, director of the UCLA Brain Tumor Imaging Laboratory

and professor of radiological sciences, and Timothy Cloughesy, professor of neuro-oncology—plan to target the epidermal growth factor receptor, a protein that is mutated in about 60% of people diagnosed with glioblastoma.

Previous attempts have had limited success improving patient outcomes due to drugs’ inability to cross the blood-brain barrier and target genetic alterations in the protein that are unique to glioblastoma. To overcome these obstacles, the researchers have developed ERAS-801, a brain-penetrant inhibitor that has been shown to work well in preclinical models. They are now testing the treatment in early clinical trials with patients diagnosed with this type of brain tumor.

“Brain cancer is a major issue, especially for people in the military,” Nathanson said. “We are hopeful that creating personalized treatments like this one and using advanced testing methods could help not only people with brain cancer but also with other rare diseases.”

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## Moffitt, pCare partner to bring interactive patient care to Moffitt Cancer Center McKinley Hospital

pCare and Moffitt Cancer Center have partnered for the ongoing integration and support of pCare’s end-to-end interactive patient care system into the recently opened inpatient surgical facility at Moffitt Cancer Center McKinley Hospital (*The Cancer Letter*, July 28, 2023).

“Moffitt McKinley Hospital’s extensive use of our interactive patient care solutions will enhance the overall experience through compassionate care and patient, family, and clinician collaboration,” Dave Bennett, CEO at pCare, said in a statement. “We are proud to partner with

Moffitt Cancer Center to boost patient experience and staff satisfaction by leveraging the healing potential of education, communication, and empowerment.”

Each 350-square-foot room within the 10-story building is equipped with a smart TV running pCare’s IPS—or interactive patient care system—including the Digital Whiteboard, which displays key patient and provider information, TV entertainment, and BYOD (bring your own device) and casting capabilities, allowing patients to pair their personal devices with the pCare system.

The patient engagement integration also includes Room Connect, the digital door display that shows key patient information at the entrance of their room and a bedside tablet option to easily navigate the system.

“Using pCare’s technology, we’re delivering unparalleled patient-centered care that encompasses the needs of patients and caregivers,” Christine Alvero, vice president of Hospital Operations at Moffitt McKinley Hospital, said in a statement. “The technology provides seamless integration with our existing systems and improves the overall inpatient experience for both patients and team members.”

Moffitt McKinley Hospital admitted its first patient on July 31. The expansive implementation of the IPS to enhance patient experiences and support caregivers and staff is in anticipation of the drastically increased patient volume of up to 65% expected within the community over the next 10 years.

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## Jersey Shore University Medical Center to establish phase I clinical trials unit

Hackensack Meridian Hackensack University Medical Center's John Theurer Cancer Center established a satellite phase I clinical trial program at Jersey Shore University Medical Center, providing patients access to novel drugs or combinations of drugs for those in need of new options.

"The program offers novel, first-in-human treatment options and provides new hope for patients with solid tumors who have exhausted other available therapies," Martin Gutierrez, co-chief of the Thoracic Oncology Division and director of the Drug Discovery and Phase I Unit at John Theurer Cancer Center, said in a statement. "This includes immunotherapy, developmental therapeutics, targeted therapies, and cell therapies."

John Theurer Cancer Center first expanded to Jersey Shore University Medical Center's HOPE Tower in spring 2022. The cancer center is part of the Georgetown Lombardi Comprehensive Cancer Center and is best known for having a nationally recognized blood cancers program including treatment for multiple myeloma, lymphoma, and leukemia, as well as having one of the largest nationwide Bone Marrow Transplant programs. These services are all now also available at Jersey Shore University Medical Center.

The site offers comprehensive medical and surgical oncology/hematology consultative services by national experts for all types and stages of cancer and serious blood disorders. This includes full infusion services, genomics analysis, and more, all provided in accordance with John Theurer quality standards and protocols.

## UF Health receives \$100k gift from Lyrics for Life for pediatric cancer research

University of Florida College of Medicine received \$100,000 from the Lyrics for Life Foundation, a nonprofit organization founded by the platinum-selling band Sister Hazel, and Stop Children's Cancer Inc.

The gift was awarded to Paul Castillo, an assistant professor in the division of pediatric hematology and oncology at the UF College of Medicine, earlier this month at UF Health Shands Children's Hospital.

"This support is extremely important in getting closer to a cure for pediatric cancer," Castillo said in a statement. "Thank you to those who play a critical role in our mission."

Since 2019, the Lyrics for Life Foundation has donated a total of \$400,000 to the Lyrics for Life/Stop Children's Cancer Jeffrey A. Block research award. This grant supports Castillo's development of personalized, targeted immunotherapy for T cell lymphoma and leukemia.

When Sister Hazel lead singer Ken Block was 16 years old, his brother Jeffrey was diagnosed with T-cell lymphoma. Jeffrey died after struggling with cancer for four years. Block wanted to build a platform to create awareness and support for cancer research.

"Childhood cancer is overwhelming," Block said in a statement. "I remember coming down the elevator the day my brother died. From that day forward, I wanted to make a difference."

## FUNDING OPPORTUNITIES



## FDA opens application for Orphan Products Clinical Trials Grant Program

FDA is accepting applications for its Clinical Studies of Orphan Products Addressing Unmet Needs of Rare Diseases (R01). This program is administered by the FDA's Office of Orphan Products Development.

The FDA's Orphan Products Grants Program awards grants to clinical investigators to support the development of safe and effective medical products for patients with rare diseases. Clinical trial grants for orphan products are a proven method of successfully fostering and encouraging the development of new safe and effective medical products for rare diseases and conditions.

The program has supported clinical research since 1983 and has funded clinical trials that have facilitated the approval of more than 80 products.

The deadline to submit applications is Oct. 24. The application, along with more information, can be in the grant guidelines.

# THE CLINICAL CANCER LETTER

## CLINICAL ROUNDUP



## University of Arizona Cancer Center's "Scientific Cafés" provide novel outreach

A study by University of Arizona Cancer Center researchers piloted a unique outreach strategy to foster dialogue between basic scientists and community members to demystify basic science research and facilitate culturally tailored approaches to address health disparities of vulnerable communities.

The paper, published in *Cancer Causes and Control*, analyzes the processes, experiences, and lessons learned during the establishment of the Research Outreach for Southern Arizona, or ROSA, program.

"Basic science research is critical for understanding biological mechanisms essential to advances in cancer prevention, diagnoses, and treatment. However, most of this research is conduct-

ed outside of the purview of community observation or input, leaving these research processes mysterious and subsequent findings disconnected from the communities they intend to benefit," senior author Jennifer Hatcher, UArizona Cancer Center member and professor in the Mel and Enid Zuckerman College of Public Health, said in a statement. "This study allowed us to develop strategies to build collaborations between basic scientists and Hispanic community members at the cancer center."

Researchers in the Cancer Center's Cancer Biology Program and Office of Community Outreach and Engagement partnered to develop the ROSA program. As part of the study, they formed a community working group, launched a community and student ambassador program, hosted scientific cafés, and developed a community-based survey.

The Scientific Café series provided opportunities for community members to have discussions with researchers about cancer. The first event was held at Rollies Mexican Patio, which offered convenient access for people living in neighborhoods surrounding the restaurant located on Tucson's southwest side. Joann Sweasy, director of the UArizona Cancer Center, spoke to attendees while Adalberto Renteria, medical director for the Pascua Yaqui tribe, translated for Spanish speakers.

Subsequent Scientific Cafés featured other speakers from the cancer center and included attendee surveys intended to help the ROSA team measure impact and make improvements.

"Accessibility, inclusivity and overall relevancy to the community—that's

where culture plays a huge role in ROSA's focus," Namoonga M. Mantina, the paper's first author and research program administrator in the Office of Community Outreach and Engagement, said in a statement. "The Cancer Center is the only comprehensive cancer center headquartered in Arizona. The work that happens here needs to be relevant specifically to the communities of Arizona and our catchment area of Southern Arizona, which is a beautiful, colorful, diversely cultural place."

The study also resulted in the development of a 17-member working group comprised of researchers, University of Arizona Community Advisory Board members, a cancer survivor, bilingual community members from Chicanos por la Causa and Nostros Comprometidos a su Salud, and representatives of El Rio Health, Marana Health Center, and Clínica Amistadconsists. The working group met to conceptualize new ways to reach community members.

While the study has ended, the success of the ROSA program has led researchers to continue the Scientific Café series this fall.

"ROSA helps connect people to that research that is currently taking place at the cancer center, but also does the flip side of that—it connects the researchers to the community. It benefits both sides," Mantina said.

## Lung-MAP master protocol expands trial access

As compared to conventional, stand-alone clinical trials in advanced non-small cell lung cancer, the biomarker-driven Lung Cancer Master Protocol, or Lung-MAP, has enrolled higher percentages of patients who are older, patients who are from rural or socioeconomically deprived areas, and patients who have Medicaid or no insurance.

These are some of the results of an analysis of the representativeness of the more than 3,500 patients enrolled to Lung-MAP from its 2014 launch through 2020. That work is being published in *JCO Precision Oncology*.

Riha Vaidya, of the SWOG Statistics and Data Management Center and Fred Hutchinson Cancer Center, is lead author on the analysis.

“Lung-MAP is the first protocol conducted within the [National Clinical Trials Network] as a public-private partnership,” Vaidya said in a statement. “There isn’t any published data on whether this partnership approach improves access to clinical trials over conventionally conducted trials. So, our goal was to examine the sociodemographic characteristics of patients enrolled to Lung-MAP and how they compared to other SWOG trials for advanced NSCLC.”

The Lung-MAP partnership includes NCI and its NCTN, including SWOG Cancer Research Network, along with Friends of Cancer Research, the Foundation for the National Institutes of Health, Foundation Medicine, pharmaceutical companies that provide their drugs for the study, and several lung cancer advocacy organizations. The trial provides an infrastructure for conducting a portfolio of biomarker-driven clinical trials in NSCLC under a shared screening protocol.

The team examined sociodemographic characteristics for all 3,556 patients enrolled to the Lung-MAP screening protocol between the activation of the study in June 2014 and Dec. 31, 2020.

They compared Lung-MAP participant characteristics to those from a set of 2,215 patients enrolled to other, individual clinical trials in advanced NSCLC that were conducted by the SWOG Cancer Research Network.

Compared to patients enrolled to other NSCLC studies, Lung-MAP patients were more likely to be 65 years of age or older (57.2% versus 46.3%), to live in a rural area (17.3% versus 14.4%), to live in a neighborhood classified as socioeconomically deprived based on its Area Deprivation Index score (42.2% versus 36.7%), or to have Medicaid insurance or no health insurance (of patients younger than 65, 27.6% versus 17.8%).

Patients on Lung-MAP, however, were less likely than those enrolled on other trials to be female (38.6% versus 47.2%), to be Asian (2.8% versus 5.1%), or to be Hispanic (2.4% versus 3.8%). In explaining the underrepresentation of female patients, the authors note that before 2019, Lung-MAP enrollment was limited to patients with squamous cell carcinoma, a tumor histology that is significantly more common among men.

“Our finding of improved access to clinical trials for some underrepresented patient groups provides an opportunity to examine how we can apply site and patient engagement practices from Lung-MAP to other trials so we can reach more patients,” Vaidya said. “We have more work to do, particularly regarding representation of racial and ethnic minority groups. SWOG’s DEI infrastructure will be critical in identifying and resolving barriers to trial access for these patient groups.”

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## OneOncology finalizes 25 oncology and hematology pathways

OneOncology finalized 25 unique oncology and hematology pathways and

published each pathway inside the platform’s clinical decision support tool.

OneOncology takes a physician-led approach to pathway development. Edward Arrowsmith, medical director of OneOncology’s Pathways Program, and experts from its five disease groups—gastrointestinal, genitourinary, breast, lung, and hematology—and disease subject matter experts—gynecology, head, and neck—lead in authoring OneOncology pathways.

OneOncology’s proprietary pathways are concordant with many nationally recognized evidence-based guidelines and are reviewed and updated regularly by OneOncology’s experts when data is presented at nationally recognized meetings or in peer-reviewed journals. Pathways are broken out by appropriate stage and treatment options by stage, including neoadjuvant, adjuvant, recurrent, locally advanced, and metastatic treatment settings, and have potential treatment options clearly listed.

“Our cancer patient population is very diverse, and therefore, pathways must account for the numerous clinical scenarios that can present in each cancer type,” Davey Daniel, OneOncology CMO, said in a statement. “OneOncology’s pathways list various treatment options ensuring they are all-encompassing and include when clinical trials are available for a specific cancer setting. The goal of OneOncology’s Pathways Program is to streamline the ordering process for physicians and efficiently put the latest medical evidence into the hands of all of our physician partners.”

Developing pathways begins with reviewing and approving all new indications or new molecular entities with the Pharmacy and Therapeutics Committee of an all-physician body called OneCouncil, which is led by OneOncology partner physicians, and then authoring a drug monograph. Once the monograph has been approved by the P&T

Committee, the newly approved agent is incorporated in draft form into the appropriate pathway and presented to the appropriate OneCouncil Disease Group. Based on efficacy and the adverse event profile of the new agent compared with other treatment options, Disease Group members decide if and where it should be added to the pathway.

“Efficacy and safety are the first priorities of our Pathways Program,” Lisa Raff, OneOncology vice president of pharmacy services, said in a statement. “While we consider contracting and cost factors within a drug class to identify treatment regimens that can provide cost savings for patients, it occurs after a clinical pathway has been approved. Overall, the goal of our pathways is to increase appropriate first-line treatment based on genomic testing and biomarkers and participation in value-based care programs, while reducing adverse events experienced by patients due to standardized regimens and appropriate supportive care.”

## Six-year outcomes from phase III CheckMate-227 show durable long-term survival with Opdivo + Yervoy in first-line treatment of mNSCLC

Six-year results from part 1 of the phase III CheckMate-227 trial demonstrate long-term, durable survival benefits of Opdivo (nivolumab) plus Yervoy (ipilimumab) compared to chemotherapy in the first-line treatment of patients with metastatic non-small cell lung cancer, regardless of PD-L1 expression levels.

Opdivo and Yervoy are sponsored by Bristol Myers Squibb.

Follow-up results will be featured in an oral presentation and were selected for the official press program at the IASLC 2023 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer.

With a minimum follow-up of over six years, the longest reported for a phase III trial with immunotherapy in mNSCLC:

- Follow-up results of the primary endpoint population of patients with tumor PD-L1 expression  $\geq 1\%$  show that the six-year survival rate for Opdivo plus Yervoy was 22%, compared to 13% for chemotherapy.
- In an exploratory analysis of patients with PD-L1 expression  $< 1\%$ , more than three times as many patients treated with Opdivo plus Yervoy were alive at six years compared to those treated with chemotherapy.
- Among those who responded to treatment, greater proportions of patients had tumor burden reduction  $\geq 80\%$  with Opdivo plus Yervoy vs. chemotherapy in both the PD-L1  $\geq 1\%$  and  $< 1\%$  subgroups, and six-year overall survival rates for patients with tumor burden reduction  $\geq 80\%$  with Opdivo plus Yervoy were higher compared to chemotherapy.
- The safety profile for the dual immunotherapy combination Opdivo plus Yervoy remained consistent with previously reported data from this trial and was manageable with established protocols, with no new safety signals identified.

“Immunotherapy has transformed the treatment of advanced lung cancer, and thankfully, a diagnosis no longer means the same thing as it used to for many patients,” Solange Peters, professor and chair of medical oncology and the

thoracic malignancies program in the Department of Oncology at the University Hospital of Lausanne in Lausanne, Switzerland, said in a statement. “With these six-year results, we are seeing remarkably sustained and durable clinical survival benefits with nivolumab plus ipilimumab year-over-year. The long-term efficacy seen with the dual immunotherapy regimen in CheckMate-227 reinforce the importance of nivolumab plus ipilimumab to transform outcomes for appropriate patients with metastatic non-small cell lung cancer.”

Opdivo plus Yervoy-based combinations have shown significant improvements in OS in six phase III clinical trials in five tumors to date: metastatic NSCLC, metastatic melanoma, advanced renal cell carcinoma, malignant pleural mesothelioma and esophageal squamous cell carcinoma.

## Intensity-modulated radiation therapy provides long-term benefits in NSCLC

Intensity-modulated radiation therapy should be the preferred choice when treating patients with locally advanced non-small cell lung cancer, as it reduces radiation exposure to the heart and lungs, according to researchers at MD Anderson Cancer Center.

Results from a long-term secondary analysis of the NRG Oncology-RTOG 0617 phase III study, with a median follow-up of 5.2 years, revealed that patients receiving IMRT had a more than two-fold reduction in severe lung inflammation compared to those who received 3D-conformal radiotherapy—3.5% versus 8.2%.

The findings were presented at the International Association for the Study of Lung Cancer 2023 World Conference on

Lung Cancer by Stephen Chun, associate professor of radiation oncology at MD Anderson.

“IMRT spared more normal tissue than 3D-CRT, which translated into a clinically meaningful benefit to patients,” Chun said in a statement. “Despite historical concerns of IMRT generating a low-dose radiation bath to a large area of normal lung tissue, we found no excess cancers, increased adverse events, or survival detriment over the long term related to this approach.”

For decades, 3D-CRT has been the standard of care for locally advanced lung cancer when surgery is not an option. However, it is less precise than IMRT, which sculpts and molds radiation beams to tumor targets, reducing radiation exposure to certain organs.

The NRG Oncology-RTOG 0617 study enrolled 482 NSCLC patients from 2007 to 2011 and compared a high dose of radiation (74 Gy) to a standard dose (60 Gy). All patients underwent concurrent chemotherapy (carboplatin/paclitaxel, with or without cetuximab) and either 3D-CRT (53%) or IMRT (47%).

Although patients treated with both techniques had similar survival rates, closer inspection of the data demonstrated a correlation between survival and radiation exposure to the heart. IMRT treatment plans achieved significantly lower cardiac radiation doses.

Both the 3D-CRT and IMRT groups had similar rates of new cancer development over time. Scientists also saw no evidence that age impacted survival, meaning that age is no reason to exclude elderly patients from curative-intent chemoradiation for locally advanced NSCLC.

“The data from our study makes a compelling argument that we should use IMRT for locally advanced lung cancer. As a randomized clinical trial comparing

3D-CRT and IMRT is unlikely to be performed, this study represents the strongest prospective evidence we will ever have in support of IMRT,” Chun said.

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## Rybrevent drug combo demonstrates durable PFS in second-line EGFR-mutated NSCLC in CHRYSALIS-2 cohort

Follow-up results from the phase Ib/II CHRYSALIS-2 study cohort evaluating the safety and tolerability of the combination of Rybrevent (amivantamab-vmjw)—a bispecific antibody targeting epidermal growth factor receptor and mesenchymal-epithelial transition—with lazertinib, an oral third-generation EGFR tyrosine kinase inhibitor, plus platinum-based chemotherapy (carboplatin and pemetrexed) in patients with relapsed/refractory non-small cell lung cancer and EGFR mutations, showed that the drug combination led to durable progression-free survival.

The combination of Rybrevent and lazertinib with chemotherapy yielded an objective response rate of 50%, with 11 out of 20 patients remaining on treatment. Median duration of response was not reached after a median follow-up of 13.1 months.

Median PFS was 14 months. Eight of 10 responders had a response duration of at least six months. Five patients were treated beyond progression, with a median incremental treatment duration of 4.2 months. The most common treatment-emergent adverse events included low white blood cell count, rash, and infusion-related reactions.

These findings were presented at the International Association for the Study

of Lung Cancer 2023 World Congress on Lung Cancer.

“Often, patients with EGFR-mutated NSCLC develop resistance to treatment during the course of therapy. Resistance in patients is typically diverse and polyclonal, meaning their tumors can have more than one type of resistance caused by different pathways. These variables can make their disease much harder to control and treat with targeted therapy alone,” Se-Hoon Lee, professor of medicine at the Samsung Medical Center and Sungkyunkwan University School of Medicine and presenting author, said in a statement. “These long-term follow-up data from the CHRYSALIS-2 study in patients with previously treated EGFR-mutated NSCLC demonstrate the importance of treatment strategies that combine chemotherapy with targeted therapy to better address complex resistance patterns after treatment with third-generation EGFR TKIs.”

Rybrevent is sponsored by the Janssen Pharmaceutical Companies of Johnson & Johnson.

CHRYSALIS-2 (NCT04077463) is an ongoing, multicohort, clinical study evaluating Rybrevent in combination with lazertinib in patients with advanced NSCLC with EGFR exon 19 deletion mutations or L858R activating mutations.

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## UC Irvine-led study links low-dose radiation to higher cancer risk

Long-term exposure to low-dose radiation is linked to an increased risk of cancer, according to a study led by the University of California, Irvine. In the U.S., radiation exposure for the average person doubled between 1985 and 2006, mainly from medical imaging

procedures such as CT scans, highlighting the need for its judicious use.

Published in *The British Medical Journal*, the research found that the cancer death rate grew by more than 50% per Gy, or gray, the unit of absorbed dose of ionizing radiation. This is larger than estimates currently underlying radiation protection. The paper marks another milestone in the International Nuclear Workers Study, which has followed 309,932 industry workers to study their causes of death.

“We wanted to strengthen the scientific basis for radiation protection by directly studying settings where low-dose exposures occur,” corresponding author David Richardson, professor of environmental and occupational health with UCI’s Program in Public Health, said in a statement. “Understanding those associations is essential to inform decisions about medical and commercial uses of ionizing radiation, exposure limits for the public, and workers.”

The study cohort included workers who were hired in the early years of the Manhattan Project and were employed at nuclear sites in France, the United Kingdom, and the U.S. They were monitored with radiation badges that measured their exposures, enabling researchers to examine the association between dose and deaths due to cancer. Of the 103,553 deaths, 28,089 were due to solid cancers, with an estimated 52% higher mortality rate per Gy of cumulative dose.

Currently, studies of atomic bomb survivors are the primary basis for establishing protection measures. But their exposure differs greatly from that typically encountered by workers, patients and members of the public. This long-term study provides estimates of the association between low-dose exposure and cancer based on some of the world’s most informative cohorts of radiation workers.

“Contrary to the trend of reducing or removing exposure to carcinogens once we have recognized them, the public’s exposure to ionizing radiation has increased over the past few decades and remains elevated,” Richardson said. “Understanding the risks associated with low-dose radiation is crucial for guiding policy.”

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## **Kisqali reduced the risk of cancer recurrence while maintaining QOL in phase III study**

Patient-reported outcomes data from the phase III NATALEE trial, presented at the European Society for Medical Oncology Virtual Plenary, show that a broad population of patients with stage 2 and 3 hormone receptor-positive/human epidermal growth factor receptor 2-negative early breast cancer maintained health-related quality of life during treatment with Kisqali (ribociclib) plus endocrine therapy.

Kisqali is sponsored by Novartis.

“Treatment in early breast cancer is physically and emotionally arduous, and afterwards people diagnosed with EBC struggle to balance the worry of their cancer returning with the burden of managing adjuvant treatment,” Peter A. Fasching, professor of gynecology and obstetrics translational medicine at the University Hospital Erlangen and Comprehensive Cancer Center Erlangen-EMN and NATALEE trial investigator, said in a statement. “The patient-reported outcomes from NATALEE reinforce Kisqali as a potential adjuvant option that reduces the risk of cancer returning without compromising patients’ well-being, mental health or physical abilities.”

Patients treated with Kisqali plus ET for up to three years maintained their physical functioning and global health scores when compared to both their baseline scores and to patients treated with ET alone, demonstrating that patients maintained their overall HRQoL when treated with adjuvant Kisqali.

“No patient should have to choose between maintaining their quality of life and doing everything they can to remain cancer free,” Jeff Legos, executive vice president and global head of oncology and hematology development at Novartis, said in a statement. “These patient-reported outcomes add to the wealth of efficacy and tolerability data from the NATALEE trial suggesting Kisqali is a potential adjuvant treatment of choice for a broad range of patients with HR+/HER2- EBC, including those with node-negative disease. Kisqali could enable patients with EBC to live well with greater peace of mind.”

Further analysis of the NATALEE trial is ongoing, and additional data will be shared at upcoming medical meetings.

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## **Nivolumab + ipilimumab more effective in immunotherapy-resistant melanoma than ipilimumab alone**

A multicenter phase II clinical study conducted by the SWOG Cancer Research Network suggests that combination ipilimumab and nivolumab can be an effective second-line therapy for patients with an aggressive and deadly type of melanoma that is resistant to PD-1 inhibitors.

The findings were reported in *Nature Medicine*.

In clinical trials, the investigators found that the combination therapy extended progression-free survival and helped overcome resistance to prior immunotherapies, allowing more patients to benefit from the treatment. The combination also showed a greater overall response rate to treatment compared to those who received the current standard therapy of ipilimumab alone.

“The results are practice-changing,” Antoni Ribas, the study’s senior author, a professor of medicine at the David Geffen School of Medicine at UCLA, and director of the UCLA Health Jonsson Comprehensive Cancer Center’s Tumor Immunology Program, said in a statement. “The combination approach should be the preferred drug regimen for people with cancer that has not responded to prior immunotherapy treatment.”

Currently, patients with advanced metastatic melanoma are treated with PD-1 inhibitors as a first-line defense. While these checkpoint inhibitors have been a significant advancement for treating people with a variety of advanced cancers, more than 50% of metastatic melanoma tumors are resistant to the drug. When resistance occurs, patients are often switched to CTLA-4 inhibitors.

Before this study, it was unclear whether patients whose cancers are resistant to the PD-1 inhibitors can continue the PD-1 agent in combination with a CTLA-4 inhibitor or if they should be switched to a CTLA-4 inhibitor alone.

“The combination had the potential to better activate the immune system against cancer by simultaneously blocking two main immune checkpoints, increase the immune infiltration in the cancer and thereby overcome resistance to anti-PD-1 alone,” said Ribas, who is also a member of the Eli and Edythe Broad Center of Regenerative Medicine and Stem Cell Research.

To see if a combination approach is more effective than using CTLA-4 inhibitors alone as a second-line therapy, researchers enrolled 91 patients in the multicenter clinical trial who had already been treated with an anti-PD-1 immunotherapy drug and had not received an anti-CTLA-4 drug. All of the patients enrolled had cancer that had not responded to the current therapy. Sixty-eight patients were randomly assigned to receive the combination of ipilimumab and nivolumab and 23 patients received just ipilimumab.

The team of investigators measured PFS as the main endpoint and also looked at other factors like how well the immune cells were infiltrating the tumors, how the cancer responded to the treatment, how long patients lived and side effects.

The team found the participants receiving combination therapy had a 37% improvement in PFS compared to participants who received ipilimumab alone. Patients receiving the combination treatment also had higher response rates, with 28% of patients seeing their tumor shrinking compared to only 9% of those who received ipilimumab alone.

Side effects were similar to what was previously known about this combination of drugs, with the most frequent severe adverse event being diarrhea, which happened at the same rate with ipilimumab alone or in combination.

“We found approximately one third of the patients receiving the immunotherapy combination had improved outcomes,” Ribas said. “Sequencing immunotherapy treatments as was tested in this study is the next step forward in our efforts to better tailor the treatment options while limiting exposure to side effects. Patients with advanced melanoma can get an anti-PD-1 treatment upfront and only add the anti-CTLA-4 ipilimumab if they do not respond, so only the patients that need the combination are exposed to the increased toxicities.”

## Combination immunotherapy treatment effective before lung cancer surgery, phase II study shows

Combination immunotherapy with the anti-PD-L1 monoclonal antibody durvalumab and other novel agents outperforms durvalumab alone in the neoadjuvant setting for early-stage non-small-cell lung cancer, according to researchers at MD Anderson Cancer Center.

The findings, published in *Cancer Discovery*, were first presented at the American Association for Cancer Research annual meeting 2022.

The multicenter, randomized phase II NeoCOAST clinical trial evaluated neoadjuvant durvalumab alone and in combination with each of the following novel immunotherapies: the anti-CD73 monoclonal antibody oleclumab, the anti-NKG2A monoclonal antibody monalizumab, and the anti-STAT3 antisense oligonucleotide danvatirsen. While the study was not statistically powered to compare arms, all combinations resulted in numerically higher major pathological response rates than with durvalumab monotherapy.

“This study builds on the growing evidence that combination immunotherapy has a role in the neoadjuvant setting for this patient population,” Tina Cascone, associate professor of thoracic/head and neck medical oncology and lead author of the study, said in a statement. “Ultimately, we want to give patients a chance to live longer without their cancer returning.”

The NeoCOAST trial adds to recent progress in neoadjuvant treatment



for NSCLC, including the phase II NEO-STAR study results published in *Nature Medicine*, which showed nivolumab and ipilimumab together induced higher responses than nivolumab alone, and the March 2022 approval of nivolumab combined with platinum-based chemotherapy from the Checkmate-816 study. The durvalumab combinations tested previously in the phase II COAST trial were shown to be effective in unresectable stage III NSCLC, providing rationale for testing in earlier stage disease.

The NeoCOAST study enrolled 84 patients with untreated, resectable, stage 1-3A NSCLC, between March 2019 and September 2020. Most patients were male (59.5%) and had a smoking history (89%).

The median age was 67.5, and the racial breakdown was 89% white, 6% Black, 2% Asian, and 2% other. Eighty-three patients received one 28-day cycle of neoadjuvant durvalumab alone or combined with another therapy.

The primary endpoint was investigator-assessed MPR, defined as  $\leq 10\%$  residual viable tumor cells in the resected tumor tissue and sampled nodes at surgery.

The investigators assessed pathological complete response, or complete disappearance of viable tumor cells, as a secondary endpoint. Exploratory endpoints included tumor, fecal, and blood biomarkers.

All combinations had numerically higher rates of MPR and pCR than monotherapy, and there were no statistically significant differences in responses between the combination arms.

For the patients who received durvalumab monotherapy, MPR occurred in 11.1% and pCR in 3.7%, which is comparable to results from other monotherapy studies.

MPR rates for combination therapy ranged from 19% (oleclumab) to 31.3% (danvatirsén), and pCR rates ranged from 9.5% (with oleclumab) to 12.5% (with danvatirsén). For combination therapy with monalizumab, MPR was 30% and pCR was 10%.

The safety profile in the durvalumab monotherapy arm (treatment-related adverse events in 34.6% of patients) was similar to previously published data for anti-PD-1/PD-L1 antibodies. No new safety signals were identified with any of the combination regimens (treatment-related adverse events seen in 43.8% to 57.1% of patients).

MPR was associated with baseline tumor PD-L1 expression of  $\geq 1\%$  in the oleclumab and monalizumab combination arms. In the oleclumab combination arm, high baseline CD73 expression was associated with pathological tumor regression, and treatment decreased CD73 expression on tumor cells, as previously observed in other studies.

The oleclumab combination also was associated with greater natural killer and CD8 T-cell density in the tumor center on treatment compared with baseline, suggesting an increased infiltration of effector cells in the tumor microenvironment.

Updated translational studies on tumor tissues and blood samples revealed the impact of neoadjuvant treatment on the immune system.

Transcriptome analysis on pre- and post-treatment samples showed an up-regulation of genes associated with cytotoxicity, tertiary lymphoid structures and lymphocyte recruitment, all indicators of an activated immune response.

The number of patients with no detected circulating tumor DNA increased progressively from pre- to post-treatment and post-surgery follow up,

highlighting the relationship between decreasing ctDNA levels and improved patient outcomes. Notably, surgery was the most effective intervention to result in clearance of ctDNA.

Researchers also found an enrichment of beneficial bacteria in the gut microbiome of patients who achieved MPR. These bacteria were previously associated with a favorable immunotherapy response across several cancer types.

“Our study is a testament to how clinical trials designed with translational findings in mind can support the rapid advancement of novel immune-based combinations to larger scale studies,” Cascone said. “I’m encouraged by these early findings as we work toward reducing the risk of recurrence and increasing cure rates for patients with early-stage non-small cell lung cancer.”

Limitations of the study include the exploratory nature of the endpoints, small sample sizes, and investigator-assessed outcomes without central review.

Based on these results and the recent approval of neoadjuvant nivolumab plus chemotherapy, the team has launched a follow-up randomized clinical trial, NeoCOAST-2, with Cascone serving as the global principal investigator.

The trial is now enrolling patients with resectable, stage 2A-3A NSCLC to receive neoadjuvant durvalumab combined with chemotherapy and either oleclumab or monalizumab or other novel and promising immuno-oncology agents, followed by surgery and adjuvant durvalumab plus oleclumab or monalizumab or other immuno-oncology agents.

The study was funded by AstraZeneca, which developed durvalumab, oleclumab, and monalizumab (with Innate Pharma).

## Enhanced recovery program successfully reduced opioid use after pancreatic cancer surgery

By improving hospital care pathways, researchers from MD Anderson Cancer Center successfully reduced inpatient opioid use by 50% after pancreatic cancer surgery and cut the median opioid prescription volumes at discharge to zero.

This approach, described in a study published today in *JAMA Surgery*, could help reduce the risk of long-term opioid dependence in patients.

In this cohort study, which involved 832 patients undergoing pancreatic resection surgery, the researchers investigated how making incremental modifications to post-surgery procedures affected the amounts of opioids used by inpatients and at the point of discharge.

In less than four years, the total inpatient oral morphine equivalents decreased from a median of 290 mg to 129 mg, while OME at discharge decreased from a median of 150 mg to 0 mg. Over 75% of patients were discharged with  $\leq$  50 mg OME, which is fewer than 10 pills.

“Patients not regularly taking opioids are at risk of developing a new dependence after surgery, and excess pills also create a risk of misuse by family members or others in their community,” senior author Ching-Wei Tzeng, associate professor of surgical oncology, said in a statement. “Pancreatic cancer surgery can be a painful operation with a difficult recovery. This study shows that, even in this setting, easy-to-implement strategies can achieve effective pain control for our patients without putting them at risk for opioid dependence.”

Pancreatic cancer surgery is considered one of the most complex abdominal operations a patient might undergo because it affects multiple organs simultaneously, which results in an expected level of pain during the early recovery period.

However, the use of opioids can be reduced by using nerve block procedures, non-opioid medications—such as muscle relaxers and anti-inflammatories—and early patient mobilization. These low-risk, low-cost maneuvers often are not used because opioids are easy to prescribe.

However, opioid misuse and addiction have become serious public health issues, and medical professionals are increasingly mindful of their prescribing practices.

The study included three consecutive cohorts, each with iterative revisions to post-surgical clinical pathways, from 2018 to 2022. After establishing a baseline and reducing length of stay, the team updated patient-provider education handouts, limited intravenous opioids, suggested a three-drug non-opioid bundle, and implemented a “5x-multiplier” (equal to OME over the last 24 hours multiplied by 5) to calculate an appropriate amount of opioids to prescribe at discharge.

Median pain scores remained  $\leq$  3 out of 10 in all cohorts, with no differences in post-discharge refill requests. Most patients did not require opioid refills after discharge, and there were no differences between cohorts. A subgroup analysis separating open and minimally invasive cases showed similar results in both groups.

Trial participants underwent 541 pancreatoduodenectomies, 285 distal pancreatectomies and six other pancreatectomies.

The median age was 65 years and 611 patients were white, 90 were Hispanic, 58 were Asian, 56 were Black, and 17 were “other.”

“Our enhanced recovery program, which includes generalizable protocols to reduce reliance on opioid medications, is the first to demonstrate continuous decreases in opioid use and distribution after pancreatic surgery,” Tzeng said. “By making purposeful, successive improvements to existing processes, we showed that we can reduce the amount of opioids patients need after a major surgery while ensuring they recover well without any extra costs.”

## Investigators devise test to identify brain tumors from cerebrospinal fluid

Researchers with the Johns Hopkins Kimmel Cancer Center, the Johns Hopkins University School of Medicine and four other institutions have developed a molecular test to identify the presence of brain tumors by measuring abnormal genetic material shed by tumors and circulating in cerebrospinal fluid.

A description of the work was published Aug. 15 in *Cell Reports Medicine*.

Typically, brain tumors are assessed through MRI imaging and biopsies. The novel test, called Real-CSF, or repetitive element aneuploidy sequencing in CSF, assesses aneuploidy—chromosome copy number alterations found in cancers—in over 350,000 regions of the genome simultaneously.

A companion bioinformatics algorithm and machine-learning process allows researchers to identify in as little as 2 milliliters of CSF if cancers are present and what molecular characteristics they demonstrate.

In laboratory evaluations of the test in 280 CSF samples from patients, some with brain or other cancers and some without cancer, Real-CSF correctly iden-

tified 67% of 184 cancerous brain lesions and 96% of 96 noncancerous lesions.

This analysis was more likely to correctly identify cancers than cytology, the standard of care. Of 121 patients with cancer in whom cytology results were available, only 28 (23%) were detected by cytology, whereas Real-CSF correctly detected 69% of cancers in this group.

If validated in additional studies and clinical trials, Real-CSF could be used to help clinicians distinguish between cancerous and noncancerous lesions, and provide information regarding how brain tumors are responding to treatment, according to senior study author Chetan Bettegowda, the Jennison and Novak Families Professor of Neurosurgery and a professor of oncology at the Johns Hopkins University School of Medicine, director of the Metastatic Brain Tumor Center at Johns Hopkins, and medical director of the Ludwig Center for Cancer Genetics and Therapeutics.

One of the next steps is to combine the approach with other substances such as mutations in genes associated with cancer, or changes to DNA that are cancer-specific, to improve the test performance.

“The test is very simple to use, works even on a limited amount of CSF and is inexpensive relative to many of the other liquid biopsy approaches on the market,” Bettegowda said in a statement. “With those characteristics, we were quite pleased that we had such a robust performance.”

## Vitamin C, D supplements led to fewer complications in AML, no OS benefit

Patients with acute myeloid leukemia who received vitamin C and D supple-

ments while undergoing intensive chemotherapy had lower rates of complications, such as infections, bleeding, and inflammation, when compared with similar, previously treated patients who did not receive these supplements.

Moreover, while the study showed no difference in survival between the two groups, a subgroup analysis showed that among patients with a genetic mutation known as NPM1—found in about one in three patients with AML—the risk of death was nearly 50% lower among those who were taking the supplements.

The results of the study were published in *Blood Advances*.

“To the best of our knowledge, this is the first study to examine the potential effects of vitamin C and D supplementation during intensive chemotherapy for AML,” Christian Récher, of the University Cancer Institute of Toulouse in France and the study’s senior author, said in a statement. “We have shown that supplementation is feasible and safe and may help reduce some significant adverse events associated with intensive chemotherapy, which is a clear benefit for patients.”

Récher and his colleagues began treating all adult patients with AML undergoing intensive chemotherapy with vitamin C and D supplements, based on the findings of several previous studies. One of these studies suggested that higher vitamin D levels prior to a donor stem cell transplant reduced the risk of a post-transplant relapse in patients with AML, while two laboratory studies indicated that vitamin C supplementation could suppress the development of leukemic cells.

In this study, the researchers compared outcomes for 431 patients with AML who received intensive chemotherapy at the University Cancer Institute of Toulouse over a five-year period; 169 pa-

tients, treated between 2018 and 2020, received vitamin C and D supplements while 262, treated between 2015 and 2018 (the control group), did not.

The median age of patients in the supplementation group was 65 and 52% were women, while in the control group, the median age was 60 and 53% were men. At the time of their AML diagnosis, most patients in both groups had low levels of vitamins C and D. Roughly a quarter of patients in the supplementation group and a third of those in the control group went on to receive donor stem cell transplants. The median follow-up period was 28.7 months for the supplementation group and 58.2 months for the control group.

In the supplementation group, vitamin D levels increased significantly from 18 ng/mL at diagnosis to 39 ng/mL at recovery from intensive chemotherapy. The normal range for vitamin D is between 20 and 50 ng/mL. No significant increase was seen in vitamin C levels likely due to a conservative regimen (6 grams per week).

During intensive chemotherapy, patients receiving the supplementation experienced lower rates of moderate to severe bacterial infections (27.2% versus 35.1% in the control), bleeding (1.8% versus 5.7% in the control), and potentially life-threatening inflammation of the immune system (1.8% versus 8.8% in the control). Median overall survival was 34.5 months, median survival without a relapse was 20.6 months, and the cumulative incidence of relapse was 46.4%. No significant differences between the two groups were observed when the researchers analyzed outcomes for all treated patients combined.

However, a subgroup analysis found that patients in the supplementation group with an NPM1 mutation—the most common mutation found in 30% to 35% of patients with AML—had a 48% reduced risk of death compared

with patients who did not have the mutation. Further studies are needed to identify the mechanism responsible for this survival difference, Récher said.

Récher and his team were especially surprised by the improved survival in patients with an NPM1 mutation who received the supplements but cautioned that this association requires confirmation in a larger, randomized study.

The study has several limitations. It was a retrospective study conducted at a single institution that compared outcomes for patients treated before and after the institution introduced supplementation for all adult patients undergoing intensive chemotherapy for AML. The study also involved a relatively small number of patients. Additionally, because all patients in the supplementation group received both vitamin C and vitamin D, the researchers could not analyze the independent effect of each vitamin or the value of combining them.

Despite these limitations, Récher said, “Our results are encouraging and support prospective clinical trials of vitamin C and D administration in AML patients.”

As always, patients should review with their care teams the medications they take, including any over-the-counter medications, vitamin and dietary supplements, and ask before starting specific supplements.

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## Blocking proteins could pull the plug on power for colon tumors

A team of scientists at VCU Massey Cancer Center discovered a previously unknown interaction between proteins that is responsible for supplying energy to tumor cells and could hold significant

implications for the development of future treatments for colon cancer.

The study’s findings were published in *Cell Reports*.

“This study is really exciting because we may be able to use these findings to inform the development of an entirely new cancer drug right here at Massey,” study author Can Senkal, a member of the cancer biology research program at Massey and an assistant professor in the Department of Biochemistry and Molecular Biology at the VCU School of Medicine, said in a statement.

The study focused on a class of fatty compounds known as ceramides. Ceramides regulate a number of vital cellular functions, and many cancer drugs stimulate ceramide generation to help fend off disease. When that production of ceramide is cut off, cancer cells can survive and grow more efficiently.

Senkal and his team began extensively screening cells in the lab to identify what proteins regularly interact with ceramide-producing proteins to identify potential patterns that could warrant further investigation.

There are six enzymes responsible for the generation of ceramide—ceramide synthase 1 through 6.

Through their research, Senkal’s team observed that ceramide synthase 1, or CerS1, was highly interactive with a particular protein known as heat shock protein 27. Heat shock proteins act like chaperones for other proteins to retain their full function; however, an overabundance of them can tip the scales and prevent ceramide synthases from doing their job.

The researchers also noticed that Hsp27 activity was higher in many colon cancer cells while at the same time CerS1 activity was significantly lower.

“There is this yin-yang kind of relationship, which gave us the idea to follow it,” Senkal said in a statement. “Hsp27 is like the bad guy holding back the good guy, CerS1.”

Through the study, they identified a specific biological mechanism through which Hsp27 interacted with and inhibited the function of CerS1 in colon cancer cells. By deliberately blocking the activity of Hsp27 in these cells, the researchers confirmed the decreased presence of Hsp27 led to a heightened reactivation of CerS1, which in turn forced a reduction in mitochondrial function.

“Cancer cells rely on mitochondria to have the energy to multiply. Without it, the cancer cells can no longer sustain the amount of energy they need and die,” Senkal said.

By blocking the function of these heat shock proteins, they were essentially able to reactivate the cellular hand that could pull the plug on the power source connected to the cancer, Senkal said.

This revelation led the study authors to suggest that Hsp27 could be a primary target in the creation of novel therapies for colon cancer.

“We can really go after these protein-protein interactions and precisely reactivate certain enzymes while we don’t touch others,” Senkal said. “We hope to demonstrate this connection in other tumors as well, which might better represent the patient population in Massey’s catchment area.”

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## Sylvester researchers help identify mechanisms by which MM escapes targeted immunotherapy

Researchers at Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine are part of an international team of scientists who identified mechanisms by which some multiple myelomas become resistant to initially effective T-cell therapies.

Targeted T cells can be rendered useless if the antigen they're tracking mutates, essentially disappearing from the radar screen. Here, the researchers report mutations that thwart immunotherapies engineered to seek out two targets in multiple myeloma, allowing previously treated cancers to adapt, escape treatment, and relapse.

"Recognizing these mutations and gaining a clearer understanding of the resistance mechanisms to these potent immunotherapies is pivotal," Francesco Maura, whose lab at Sylvester conducts myeloma computational and translational research, said in a statement. "This knowledge plays a crucial role in devising tailored strategies and making informed choices regarding the selection of products and targets for individual patients."

Maura is a senior author of the study's report, which was published in *Nature Medicine*.

"Antigenic drift" is well established as a mechanism that tumors employ to develop resistance to immunotherapy. In this study involving 30 patients, the researchers focused on changes occurring in two potential targets on plasma cells: B cell maturation antigen and G-protein coupled receptor family C group 5 member D. Chimeric antigen receptor T cells, or CAR-T cells, and "bispecific T-cell engagers," called TCE, are immunotherapies that can be engineered to target these antigens and have shown promise in treating relapsed or treatment-resistant multiple myeloma.

Over time, however, and as the cancer cells change, effectiveness often wanes.

Few studies have been done to identify the reasons for this diminishing clinical response—and this is believed to be the first genomic study of "intrinsic" mechanisms of cancer cells that permit antigen escape in patients who relapsed after undergoing these immunotherapeutic approaches.

"We identified distinct and novel genomic events responsible for resistance to anti-BCMA and anti-GPRC5D immunotherapies," C. Ola Landgren, who conducts computational and translational research in myeloma and is a co-author of the *Nature Medicine* paper.

"One important aspect of our findings is that mutations in the extracellular domain of BCMA have a distinct impact: They impede the binding of the therapeutic T cells without exerting any influence on the protein's expression or downstream signaling pathways. This finding revealed that the proportion of patients with myeloma who experience relapse due to antigen escape is considerably more extensive than initially anticipated," Landgren said.

The discovery of these mutational events that precipitate multiple myeloma relapse underscores the critical need to screen patients for these variants, according to the article. Additionally, detailed characterization of these binding interactions will permit the rational design of next-generation T-cell redirecting agents and inform the optimal sequencing and combination of these immune-therapeutic approaches, the authors said.

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## Study suggests immune system plays role in extended PFS in MM

A study from researchers with Sylvester Comprehensive Cancer Center at

the University of Miami Miller School of Medicine and other top-tier cancer centers highlights the vital role that the immune system plays in determining the duration of patients' remission from multiple myeloma.

Their findings, published Sept. 2 in *Nature Communications*, suggest that the health of patients' immune systems may determine how long they will experience progression-free survival from this deadly blood cancer.

Additionally, the researchers were pleasantly surprised to discover that patients' immune systems could recover to a healthy state if their disease was brought into deep remission through therapy.

"Our study underscores how critically important the immune system is to patients' ability to respond favorably—and achieve remission—through current therapies for multiple myeloma," David Coffey, Sylvester hematologic oncologist and researcher and the study's first author, said in a statement.

"Moreover, we discovered that the immune systems of multiple myeloma patients being treated with modern combination therapy could ultimately recover to resemble those of healthy bone-marrow donors if they were able to achieve and sustain minimal residual disease negativity," he said.

Sustained MRD negativity is defined as two consecutive negative measurements, meaning no evidence of detectable disease using validated, highly sensitive MRD tests, at least one year apart during maintenance therapy.

"We found a strong correlation between sustained MRD negativity and prolonged survival," C. Ola Landgren, chief of the Division of Myeloma at Sylvester and senior study author, said in a statement. "In fact, patients who were treated with modern combination ther-

apy and achieved and sustained MRD negativity for at least two years were highly likely to remain free from multiple myeloma 10 years later.”

Landgren added that a small subset of patients that converted from MRD negativity to MRD positivity within a year were 14 times more likely to experience disease progression.

“We have already launched a follow-up study designed to characterize myeloma cell biology and host immune cell biology of patients with long-term, sustained MRD negativity versus patients who convert from MRD negativity to MRD positivity,” he said. “Ultimately, we are seeking to understand underlying mechanisms to develop curative strategies.”

Previously, the researchers had published results of a phase II clinical trial investigating the dynamics of MRD during maintenance therapy for patients with newly diagnosed multiple myeloma following unrestricted first-line therapy.

For this correlative study, researchers comprehensively profiled the immune microenvironment of 23 patients with newly diagnosed multiple myeloma receiving the drug lenalidomide and compared patients achieving MRD negativity one year after treatment to those who never achieved a MRD-negative state or were unable to sustain it.

To account for differences in treatment histories, researchers also conducted a separate analysis to examine the potential impact of patients receiving the standard therapy of high-dose chemotherapy followed by autologous stem-cell transplantation versus other treatment regimens.

“One hypothesis of our and others’ research is that there may be a subset of patients who can attain a functional cure and therefore halt maintenance

therapy,” Coffey said. “But the challenge remains to properly identify those patients ready for treatment de-escalation. Our team’s new study was designed to address this important topic.”

The authors said that future research with a larger patient population is needed to explore whether treatments aimed at enhancing the immune system can improve the response to existing myeloma therapies, leading to improved patient outcomes overall.

## Gene therapy study identifies potential new treatment for liver cancer

Gene therapy that induces the body to create microRNA-22, or miR-22, a naturally occurring molecule, successfully treated mice with hepatocellular carcinoma in a study at the UC Davis Comprehensive Cancer Center. The miR-22 treatment also reduced liver inflammation and produced better survival outcomes compared to the FDA-approved liver cancer treatment lenvatinib.

The findings were published in *Molecular Therapy*.

“This research introduces miR-22 gene therapy as a promising and innovative approach for treating hepatocellular carcinoma,” Yu-Jui Yvonne Wan, senior author of the study, said in a statement. Wan is a distinguished professor and vice chair for research in the UC Davis Department of Pathology and Laboratory Medicine. “The study’s findings suggest that miR-22 therapy could provide better survival outcomes, enhance anti-tumor immunity, improve metabolism and reduce inflammation.”

The University of California filed a patent application for Wan’s discovery of miR-22 for treating hepatic and

metabolic diseases. The patent is currently pending.

MicroRNAs are small molecules that contain RNA. They are “non-coding,” meaning they do not make proteins like some other RNA molecules. In the case of miR-22, it acts like a brake, stopping the production of certain proteins, including cyclin A, protein deacetylases, and hypoxia-inducible factor, that can fuel liver cancer growth. A lack of miR-22 is found in hepatocellular carcinoma tumors, and its levels can predict survival time for patients with the disease.

For the study, Wan and first author Ying Hu, an assistant professional researcher in Wan’s lab, used gene therapy—an inactivated adenovirus—to introduce miR-22 into mice with a single intravenous injection.

The mice treated with the gene therapy were compared with mice treated with the current FDA-approved drug lenvatinib, untreated mice, and healthy mice.

Both miR-22 and lenvatinib inhibited the progression of the liver cancer compared to untreated mice. However, the miR-22-treated mice had longer survival times without toxicity compared with lenvatinib-treated mice.

At five weeks, untreated mice had enlarged livers, making up 33.5% of their body weight. The treated mice had smaller, less diseased livers, with ratios of 10.9% (miR-22) and 12.0% (lenvatinib) of body weight.

The median survival rate was 46 days for the lenvatinib group and 50 days for the miR-22 group.

Drugs to treat hepatocellular carcinoma—sorafenib, lenvatinib, regorafenib, and cabozantinib—are associated with considerable toxicities and poor quality-of-life outcomes. The survival benefit is limited to a few months and the cost is very high.

“The positive findings from this pre-clinical study give us hope that miR-22 could be a promising alternative to treat hepatocellular carcinoma,” Hu said in a statement.

## Wistar researchers identify potential target for gastric cancers associated with Epstein-Barr Virus

Scientists at The Wistar Institute have discovered a potential target for gastric cancers associated with Epstein-Barr Virus. In a paper published in the journal *mBio*, Wistar’s Tempera lab investigates the epigenetic characteristics of gastric cancer associated with the Epstein-Barr Virus. In evaluating EBVaGC’s epigenetics—the series of biological signals associated with the genome that determines whether a given gene is expressed—the Tempera lab highlights a target that could advance as a future treatment for this type of cancer.

The work of Italo Tempera, associate professor in the Gene Expression & Regulation Program in the Ellen and Ronald Caplan Cancer Center at The Wistar Institute, and collaborators demonstrates that an epigenetically active compound called decitabine disrupts the genome of EBVaGC by epigenetically modifying the cancer’s DNA, a finding that offers the potential for a new approach to treating EBVaGC.

“What we have identified is essentially a self-destruct button within this kind of cancer, and our paper shows that we figured out how to press that self-destruct button,” Tempera said in a statement. “Normally, a latent virus that reactivates and starts to kill cells is a bad thing. But by switching that viral lytic process back

on in these cancer cells by using epigenetic signaling, we’re effectively getting the virus to kill the cancer cells that it’s responsible for in the first place.”

The research—supported by a P01-series grant from the National Institute of Health—includes scientists from The Wistar Institute, The Coriell Institute for Medical Research, and Brigham and Women’s Hospital of Harvard Medical School.

In EBVaGC, the cancer cells’ DNA is hypermethylated: the DNA contains a high percentage of cytosine with a 5-methyl group attached to it. As a silencer of gene expression, DNA methylation allows EBV to remain latent. This methylation pattern plays a significant role in regulating the EBV latency-lysis cycle within the cancer cells. DNA methylation, as an epigenetic factor, usually functions as a gene-silencing mechanism, particularly in certain regions of the genome.

To disrupt this epigenetic profile, the researchers turned to decitabine, a compound known for its ability to reduce DNA methylation levels. Tempera and his co-authors treated two cell lines that were derived from EBVaGC tumors with decitabine. The cell lines that received the treatment demonstrated massive reductions in DNA methylation across the genome relative to the control as assessed by a variety of epigenetic assay techniques.

In observing the effects of decitabine treatment on EBVaGC, Tempera’s team found a significant disruption of the cancer’s epigenetic profile. The EBV genome within EBVaGC treated with decitabine resulted in widespread, mostly uniform hypomethylation of the EBVaGC epigenome (with a few regional exceptions).

Tempera and his co-authors discovered that the hypomethylating effect of

decitabine treatment reactivated the lytic cycle of the latent EBV in the cancer cells. Because lysis is lethal to cells, the epigenetic reactivation of lysis within gastric cancer associated with EBV offers a promising potential treatment for the specific subset of EBVaGC.

“Now we know that we can use the epigenome of Epstein Barr Virus against the gastric cancer that it affects—that’s an exciting potential cancer therapy we have as a result of investigating the interplay between epigenetic patterns and disease lifecycle,” Tempera said.

### DRUGS & TARGETS



## FDA approves Akeega for BRCA-positive metastatic castration-resistant prostate cancer

FDA approved Akeega (niraparib and abiraterone acetate), a dual action tablet combining a PARP inhibitor with abiraterone acetate, given with prednisone, for the treatment of adult patients with deleterious or suspected deleterious BRCA-positive mCRPC, as detected by an FDA-approved test.

Akeega is sponsored by the Janssen Pharmaceutical Companies of Johnson & Johnson.

“As a physician, identifying patients with a worse prognosis is a priority, especially those whose cancers have a BRCA mutation,” Kim Chi, medical oncologist at BC Cancer—Vancouver and principal investigator of the phase III MAGNITUDE study. “We prospectively designed the MAGNITUDE study to identify the subset of patients most likely to benefit from targeted treatment with Akeega and to help us understand how we can potentially achieve better health outcomes for patients.”

Approximately 10-15% of patients with mCRPC have BRCA gene alterations. Patients with BRCA-positive mCRPC are more likely to have aggressive disease and may experience poor outcomes and a shorter survival time.

“The approval of Akeega brings an important treatment option to patients with prostate cancer as they consider their road ahead, and it also highlights the importance of genetic testing and precision medicine for this disease,” Shelby Moneer, vice president of patient programs and education at ZERO Prostate Cancer, said in a statement. “All individuals diagnosed with prostate cancer should consider genetic testing, especially those from racial and ethnic minority groups who tend to have worse cancer outcomes. This is imperative to close the racial and ethnic disparities in prostate cancer health outcomes.”

The FDA approval is based on positive results from the randomized, double-blind, placebo-controlled multi-center phase III MAGNITUDE study. In BRCA-positive patients treated with the combination Akeega plus prednisone, a statistically significant 47% risk reduction was observed for radiographic progression-free survival.

At the second interim analysis, with median follow-up at 24.8 months in the BRCA-positive subgroup, rPFS by central review demonstrated a consistent trend favoring Akeega plus prednisone, with a median rPFS of 19.5 months compared with 10.9 months for placebo and AAP.

Additionally, there was an observed improvement in the secondary endpoints of time to symptomatic progression and time to initiation of cytotoxic chemotherapy for Akeega plus prednisone compared with AAP alone, supported by a trend towards improvement in overall survival.

The observed safety profile of the combination of Akeega plus prednisone was consistent with the known safety profile of each FDA-approved monotherapy. Of the patients in the MAGNITUDE study with a BRCA gene alteration, 41% who received Akeega experienced a serious adverse event.

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## FDA approves new and updated indications for Temodar under Project Renewal

On Sept. 14, FDA approved updated labeling for Temodar (temozolomide) under Project Renewal, an Oncology Center of Excellence initiative aimed at updating labeling information for older oncology drugs to ensure information is clinically meaningful and scientifically up-to-date.

This is the second drug to receive a labeling update under this pilot program. The first drug that received approval under Project Renewal was Xeloda (capecitabine).

Temodar is sponsored by Merck. Full prescribing information for Temodar can be found on the drug’s label.

Project Renewal is a collaborative program that leverages external oncology experts and early-career scientists to review existing published literature and gain first-hand experience in the selection, curation, and evaluation of evidence for independent FDA review.

Project Renewal is intended to keep older, commonly prescribed oncology drugs’ labeling up-to-date, while providing transparency on FDA’s evaluation process and evidentiary standards, and improving awareness of drug labeling as an information resource.

Temodar is now approved for the following new and revised indications:

- Adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma.
- Treatment of adults with refractory anaplastic astrocytoma.

One approved indication for Temodar remains the same:

- Treatment of adults with newly diagnosed glioblastoma, concomitantly with radiotherapy and then as maintenance treatment.

Additional labeling revisions include:

- The dosage regimen is revised and updated for newly diagnosed glioblastoma and refractory anaplastic astrocytoma.
- For Temodar capsules, information on risks from exposure to opened capsules is added under Warnings and Precautions.
- Patient Counseling Information section and the Patient Information document are updated and revised.



Project Renewal is limited to updating labeling of older oncology drugs with decades of use, multiple supportive clinical studies, and substantial post-marketing experience.

## FDA, Flatiron Health renew five-year research collaboration on real-world data

Flatiron Health and FDA's Oncology Center of Excellence renewed their collaboration to jointly develop and implement specific research projects to advance the use of real-world data and explore the potential strengths and limitations of using real-world evidence for regulatory purposes. The partnership will specifically evaluate RWD study designs and analytic methods through the collaborative development of priority, clinically meaningful research questions regarding care, treatment, and outcomes of patients with cancer.

"Flatiron is honored to continue our collaboration with FDA," Javier Jimenez, chief medical officer of Flatiron Health. "Together we will explore the potential strengths and limitations of using real-world evidence through investigations of a broad set of research questions regarding the care and clinical outcomes of patients diagnosed with solid tumors and hematological malignancies."

Further, projects under this collaboration will explore approaches to define and assess fit-for-purpose relevant data on treatment exposure, patient outcomes, and covariates required to answer specific questions of interest.

As part of the research process, Flatiron's datasets will be analyzed to explore fit for purpose RWD, create

real-world study protocols using best pharmacoepidemiology practices, and conduct observational studies.

Additionally, the collaboration will enable Flatiron to provide FDA access to their datasets/platform, and highlight their suite of services, including cutting-edge analytics, scientific expertise, and strategic consulting.

## Pierre Fabre Laboratories acquires Vertical Bio

Pierre Fabre Laboratories, the French pharmaceutical and dermo-cosmetic company, announced the acquisition of Vertical Bio AG, a developer of novel cancer therapies.

With this first acquisition of a biotechnology company, Pierre Fabre Laboratories adds VERT-002 to its oncology discovery pipeline.

VERT-002 is a monoclonal antibody that acts as a degrader of c-MET. This target is a known disease driver in patients suffering from non-small cell lung cancer with mutations or amplification of MET. Deal terms were not disclosed.

Vertical Bio was founded by Versant Ventures and was launched out of the firm's Ridgeline Discovery Engine based in Basel, Switzerland. Leveraging Ridgeline's biology capabilities, Vertical Bio advanced VERT-002 through preclinical studies and towards an IND submission.

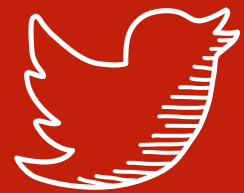
The first-in-human studies are expected to begin in 2024.

This acquisition enables Pierre Fabre Laboratories to further strengthen their R&D portfolio in precision oncology with a product about to enter

clinical development. The group has made oncology its top priority in medical care and dedicates about 80% of its R&D spendings to this therapeutic area every year.

"We are excited about the acquisition of this biotechnology company and the addition of VERT-002 to reinforce our research and development portfolio in lung cancer. This acquisition is another testimony of our commitment to invest in the discovery and development of innovative treatments in precision oncology" Eric Ducournau, CEO of Pierre Fabre Laboratories, said in a statement.

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