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HIGH SCHOOL SCIENCE COMPETITIONS SHAPED THE CAREERS OF REGENERON'S CO-FOUNDERS—NOW, THEY'RE PAYING IT FORWARD

NCI's Youth Enjoy Science (YES) program also invests in student scientists

→ PAGE 6

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Sidney Kimmel Comprehensive Cancer Center and the Department of Medical Oncology at Thomas Jefferson University (TJU)

Faculty Leadership Position in Cancer Population Research

The Sidney Kimmel Comprehensive Cancer Center (SKCCC) and the Department of Medical Oncology at TJU in Philadelphia, Pennsylvania is excited to announce a new faculty position who will serve as the Associate Director (AD) of Population Science in SKCCC and the Chief of the Division of Population Science in the Department of Medical Oncology. The AD will be a senior executive leader who will report to the director of SKCCC and the Chair of the Department. The candidate should be an accomplished funded investigator (PhD, ScD, MD, or MD/PhD) that has demonstrated ability to build multi-disciplinary teams and has an expertise and research focus in one or more of the following:

- Molecular & genetic cancer epidemiology
- Cancer risk assessment and screening
- Discovering & validating biomarkers of cancer risk, progression and prognosis
- Cancer prevention and control
- Behavioral intervention in Cancer Care
- Cancer survivorship
- Outcomes research
- Palliative care
- Smoking/tobacco use
- Geriatric Oncology
- Health Disparities in Cancer
- Implementation science

Investigators dedicated to improving the quality of cancer care for diverse populations through research who have an established track record of grant funding are strongly encouraged to apply.

The role will focus on enhancing population science research within the SKCCC and the Department; develop strategic initiative with basic, clinical, population and translational researchers throughout the Jefferson Enterprise, and expand community outreach, engagement and education efforts.

The Sidney Kimmel Comprehensive Cancer Center (SKCCC) is an NCI-designated consortium cancer center that includes researchers from Thomas Jefferson University and Drexel University. The SKCCC has just achieved comprehensive status, and its community outreach and engagement component is ranked as “exceptional”. The SKCC has a successful population science Cancer Risk and Control research program with over $13m in peer-reviewed funding and 34 full members from 15 departments at Jefferson and Drexel. Jefferson has a network of 18 hospitals in the region, providing tremendous opportunities for data science and population health research.

Recruited faculty will be provided generous start-up funds, a competitive salary, and modern facilities, along with administrative and infrastructure services. Successful candidates will get access to cancer registries, and the evolving resources of various types of cancer biorepositories developed within the cancer center. Existing investigators work in biomarkers, disparities, obesity, behavioral studies, survivorship, toxicity reduction and aging. Successful candidates will have opportunities to mentor trainees at all levels from the Jefferson College of Population Health and Drexel University’s Dornsife School of Public Health. In addition to membership in the SKCCC, primary and secondary faulty appointment(s)/affiliation(s) may be one or more departments/divisions of the Sidney Kimmel Medical College and/or the College of Population Health at Jefferson.

The SKCCC at Jefferson is located in the heart of Philadelphia with an abundance of opportunities for professional and social interactions in a vibrant urban cultural setting. Jefferson values diversity and encourages applications from women, members of minority groups, LGBTQ individuals, disabled individuals, and veterans.

Inquiries and expressions of interest should be directed to:
Gabrielle.Vartanian@jefferson.edu
FacultyRecruitment@jefferson.edu and submit an application at
https://hr.jefferson.edu/careers.html and reference job ID 9301327

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In this issue

CLINICAL ROUNDUP

DRUGS & TARGETS

High school science competitions shaped the careers of Regeneron's co-founders—now, they're paying it forward

NCI's Youth Enjoy Science (YES) program also invests in student scientists

By McKenzie Prillaman

Kate Choi grew up hearing conversations about skin cancer. Her grandparents had it, as did her cousins.

This family history with skin cancer prompted Choi to look into dermatology databases, where she noticed a dearth of data on patients with darker skin tones. Also, she learned that Black and Asian patients with melanoma have poorer prognoses than white patients with the disease.

"There's this common misconception that people with darker skin won't get skin cancer," said Choi, a student at the Potomac School in McLean, VA, who recently competed in the Regeneron International Science and Engineering Fair in Los Angeles. "There's just an extreme lack of data on basically any race or any person with dark skin."

Choi, who is Korean American, is no ordinary 17-year-old. The rising high school senior has a passion for scientific research—and is precisely the sort of young person that industry and NCI want to keep on track in their pursuit of science.

In May, Choi, who developed an AI-based algorithm to detect skin cancer on darker skin tones, joined nearly 2,000 other student scientists at Regeneron ISEF, the world's largest pre-college science competition.

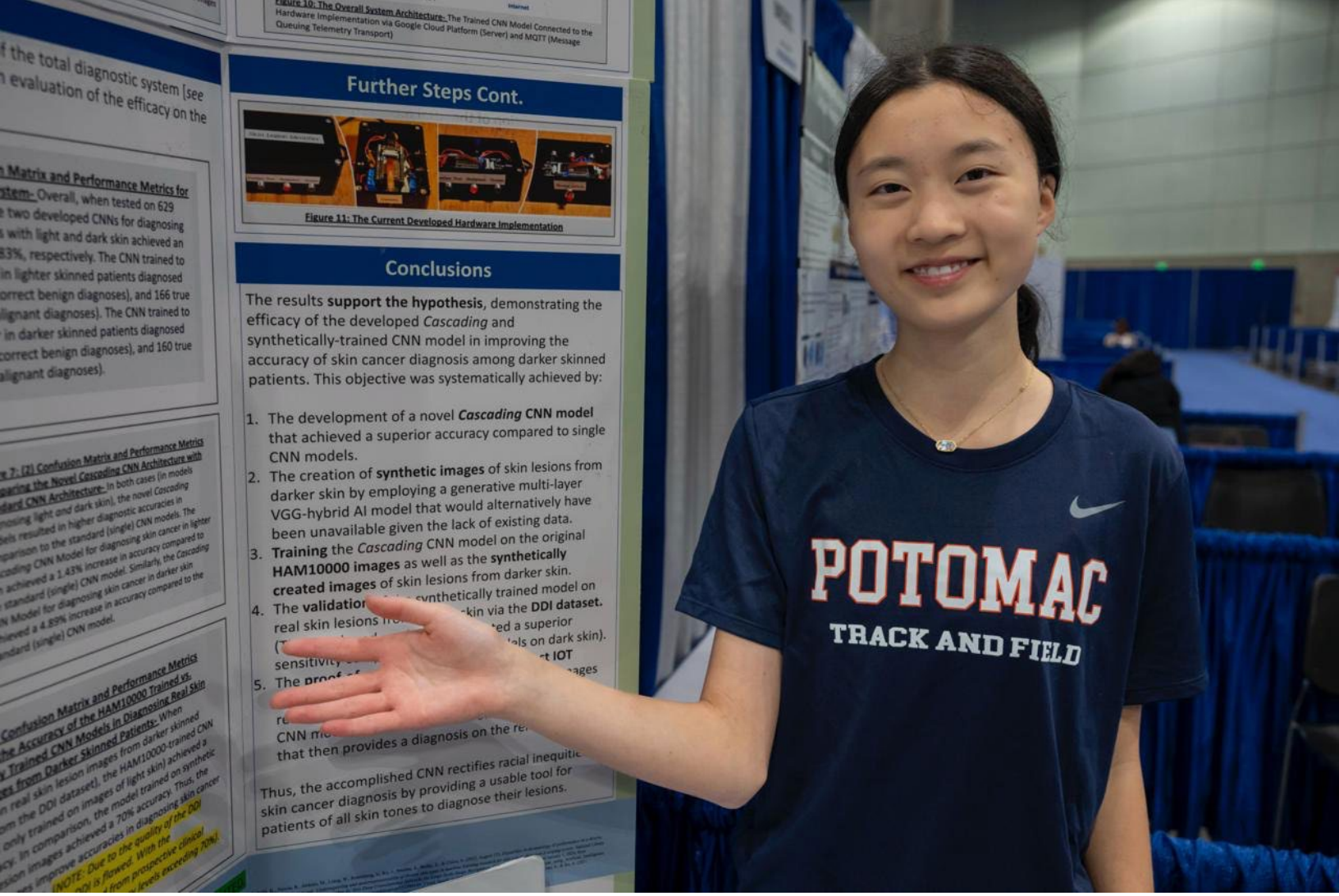
"Racial justice is just something that I'm very passionate about, especially at the intersection with medical fields," Choi said to *The Cancer Letter*. "So, I thought [competing in science fairs] was a great way for me to express my work and get some acknowledgment."

ISEF's title sponsor, Regeneron Pharmaceuticals Inc., funds the competition to excite high school students about research and to elevate award winners as role models—all to build the next generation of scientists, said George Yancopoulos, president, chief scientific officer, board co-chair, and co-founder of Regeneron.

"We recognize that there's going to be so much need, and these kids are going to have to figure a lot of things out," he said to *The Cancer Letter*. "We need the next generation."

NCI, too, plays a role in inspiring future scientists. The institute's Youth Enjoy Science program funds educational and research-based activities for students from underrepresented backgrounds to inspire them to pursue careers in cancer research.

"We believe in the power of early intervention—planting seeds—and we understand that there is a need to reach



Kate Choi with her research poster at the 2024 Regeneron ISEF competition in Los Angeles.
Photo credit: Courtesy of Kate Choi

younger minds," said Behrous Davani, chief of the NCI Center to Reduce Cancer Health Disparities Diversity Training Branch, which oversees the YES program. "We hope that we can see the fruits in 10, 15, 20, 30 years."

Designating science heroes

Yancopoulos was 13 when his grandmother developed Alzheimer's disease.

"She basically raised me," Yancopoulos said, explaining her pivotal role in the Greek immigrant family. "That helped motivate me to say, 'Hey, I want to become a scientist and cure Alzheimer's.'"

In high school, Yancopoulos started studying a protist genus's regenerative abilities, hoping to one day regenerate neurons in humans. That project earned Yancopoulos ninth place at the 1976 Science Talent Search, which is currently known as the nation's oldest and most prestigious science competition for high school students.

STS is run by the Society for Science, the same non-profit that operates ISEF. Now, both of these competitions are sponsored by Regeneron.

Yancopoulos sees his company's sponsorship as a way to back the experience that kicked off his career.

"To think that a bunch of serious top scientists thought I was good enough to get to the highest levels and even be a winner gave me confidence," Yancopoulos recalled. "Maybe I could do this. Maybe I could really be a scientist."

Winning an award at STS was a big deal at his high school.

"At most schools, the heroes are the captains of the football team," Yancopoulos said. "But at the Bronx High School of Science, the real heroes are the kids who win these science competitions."

STS has been designating the heroes that young Yancopoulos admired since its founding in 1942.

Originally sponsored by the Westinghouse Electric Corporation, the competition provides a stage for U.S. high school seniors to present original research. Today, nearly 2,000 students enter the competition each year, and 40 finalists come to Washington, DC, in March to compete for awards that include a first-place prize of $250,000.

Similarly, ISEF started in 1950 and was also first sponsored by Westinghouse. Each May, the international competition hosts around 2,000 finalists who have moved forward from local and regional fairs. These finalists gather in a U.S. city to compete for about $9 million in prizes, including a top award of $75,000.

Sometimes, these competitions provide lessons in scientific integrity. This happened at the most recent competition, soon after one finalist was named one of this year's $50,000 Young Scientist Award winners.

The Society for Science "received allegations regarding the scientific integrity" of the research project, the society said in a press release. "Per the society's defined process, a thorough investigation was immediately conducted," and the contestant ultimately "opted to withdraw his project and decline the awards," the press release said.

Although the competitions center around prestige and monetary awards, many ISEF finalists, including Choi, find the personal connections and experiences much more valuable.

"They do give out awards here, and all that," Choi said. "But I just think that being able to come here is a great opportunity in itself because of how special it is."

Choi took home a third-place prize in the biomedical and health sciences division for her skin-cancer detecting AI algorithm.

She is now finessing the hardware portion of the project, a low-cost device to image a skin lesion in question for testing by her algorithm. The algorithm provides three possible outcomes: benign, malignant, or needs further testing.

"One of these hardware devices can serve an entire community of people that does not have access to immediate health care," Choi said.

Erin Song (front left) and other ISEF finalists with George Yancopoulos (front right) at the 2024 Regeneron ISEF competition in Los Angeles.
Photo credit: Erin Song

Choi plans to pursue a research career at the intersection of biomedical science and health equity, although she is concerned about her future with NIH facing potential budget cuts—especially in an era of increasing distrust in science (*The Cancer Letter*, April 12, 2024).

Federal funding for scientific research seems to be largely a question for another day for ISEF finalists.

"The thing that I really love is the enthusiasm that I'm surrounded by—there are so many cool student projects," said another competitor, Erin Song, a recent graduate of Horace Greeley High School in Chappaqua, NY. "I really appreciate how everyone here is so dedicated to their craft and their science."

Song presented research on a novel method to identify potential drug targets for cancer treatment, and evaluation of a protein she found that could be an actionable treatment target for non-small cell lung cancer. Her project received fourth place in the biomedical and health sciences division.

"I've always been really interested in science, and specifically cancer," she said. "Cancer is going to be a disease that will plague humanity for a long time."

Song plans to pursue a pre-medical track when she starts at Georgetown University this fall, and ultimately go into health care administration.

Her career choice has been shaped by the people she met at ISEF and other competitions, she said. And Yancopoulos, in particular, left a lasting impression on her.

"He was once a student researcher," Song said. "Being able to see someone who was once in my shoes be so successful is just really inspiring."

Paying it forward

Both ISEF and STS have faced peril over the last 30 years. Westinghouse, which was failing in the 90s, handed over title sponsorship to Intel in 1997. That tech company stopped sponsoring STS less than a decade later, in 2016.

When news broke that Intel was ending its sponsorship, Yancopoulos and Leonard Schleifer, president, CEO, board co-chair, and co-founder of Regeneron—and a one-time STS contestant—went to their company's board to urge for Regeneron to take over.

"We were a much smaller company [at the time], and we really didn't have the resources to do it," Yancopoulos said. "But we also didn't want it to die."

The board shared Yancopoulos and Schleifer's fervor for the competitions. "Everybody was all in. This was a national treasure, something that was so critical for generations of scientists, and we wanted it to keep going," Yancopoulos said.

In 2016, the pharmaceutical company dedicated $100 million to STS over the next 10 years, and 2017 marked the first year of Regeneron STS.

"We're a science-led and a science-driven company, and we feel like it's our duty, our obligation, and our responsibility to pay it forward," Yancopoulos said.

Additionally, 2020 became the first Regeneron ISEF, after the company dedicated $24 million to ISEF for a five-year period starting in 2019. In 2023, Regeneron added another $34 million commitment to the international competition over the next five years.

"It's such a great full-circle story that two kids who were engaged and inspired by these very competitions are now the sponsors of the competitions," Yancopoulos said. "I'm hoping that these kids end up with the same sort of full-circle stories."

Elevating students

Competing in science fairs requires time, money, mentorship, and other resources, and for some students, conducting original research is simply not feasible. Only a small proportion of America's more than 20,000 high schools can support student research.

"Unfortunately, only a few thousand [high schools] have [research] programs and consistently produce kids who compete at these levels," Yancopoulos said.

"So, what we're trying to do—and a lot of the investment that we make—is going to try to engage and help and elevate some of the schools that don't have histories of programs," he said.

For instance, Regeneron has partnered with Cold Spring Harbor Laboratory to open an education center with laboratories for middle and high school students. The company also sponsors a research program for students attending Yonkers public high schools.

NCI, too, has been investing in the next generation of researchers at a young age. The institute has sponsored YES programs at various institutions around the country since 2017, having contributed about $41 million to the enterprise so far. They are part of the Continuing Umbrella of Research Experiences program, an initiative of NCI's Center to Reduce Cancer Health Disparities.

These programs support middle school, high school, and undergraduate-level research and educational activities to increase diversity in the cancer workforce. "The program components are designed to instruct and attract [students] to cancer research as a career path, and also to engage with the community," Davani, of the NCI center's Diversity Training Branch, said to *The Cancer Letter.*

The mission also aligns with NIH's goals to build minority health and reduce health disparities, said Sangeeta Ghosh, a program director at the NCI CRCHD DTB. "Diversifying the workforce is one of the powerful strategies to reduce these kinds of disparities."

NCI has supported more than 1,500 students—about 850 of whom were high schoolers—through 24 YES programs, Davani, Ghosh, and JoBeth McCarthy, a program director at the NCI CRCHD DTB, said in a statement to *The Cancer Letter.* In some programs, more than 90% of participants are now pursuing biomedical-related degrees, according to the statement.

"We are creating a huge cohort of students that can be role models for their peers, for their neighbors, for their family members," Davani said. "This is definitely an investment in the future, and we hope that we can nurture the program."

Taking action

The University of Kentucky Markey Cancer Center created one such education program for young scientists in 2016 through an NCI CURE supplement. That program, called the Appalachian Career Training in Oncology Program, or ACTION, has been an NCI YES program since 2018.

ACTION's high school portion focuses on students from counties in eastern Kentucky, specifically 54 counties in the Appalachian region.

"The reason we target those students in particular is [because] Kentucky has a massive cancer problem—first in the nation in overall cancer incidence and mortality rates for a long time," Na-

THE CANCER LETTER | JUNE 28, 2024 | VOL 50 | ISSUE 26

than Vanderford, director of the MCC ACTION program, said to *The Cancer Letter*. "And those rates are significantly greater in those 54 counties."

Vanderford is also an associate professor in the Department of Toxicology and Cancer Biology and director of administration at the Center for Cancer and Metabolism at UK, and assistant director of Pathway Programs and Student Success at the UK Markey Cancer Center.

Disparities in educational attainment are acutely felt in the region, too, Vanderford said. In eastern Kentucky, 19% of people age 25 and over lack a high school degree, compared to 11% of the U.S. population, according to the Appalachian Regional Commission's chartbook compiling data from the 2017-2021 American Community Survey. And only 16% of people in the area hold a bachelor's degree, compared to 34% of the U.S. population.

ACTION steps in by offering a two-year program—almost 100% free, and with a stipend—for around 20 selected students in each cohort. Every month, the students visit the UK campus for a day of activities, like lectures from guest speakers and even a ballroom dance lesson in conjunction with a discussion on wellness.

Pathologist Thèrése Bocklage (left) mentored Nolan Marcum (right) as part of the UK Markey Cancer Center ACTION program.
Photo credit: University of Kentucky Markey Cancer Center

The program's main event takes place in the summer when students stay on campus for five weeks. There, they conduct research in labs they have been matched with based on their interests, attend workshops on topics including cancer biology, clinical ethics, and career development, and shadow health professionals.

"That is really where the magic happens for a lot of the students," said Nolan Marcum, a rising senior at UK who participated in the ACTION program as a high school student and undergraduate. That summer portion is where he received mentorship from pathologist Thèrése Bocklage, who gave him the confidence to pursue a medical degree.

Marcum first applied to the ACTION program thanks to a push from teachers in his small hometown of Grayson, KY. "Neither of my parents went to college, so education wasn't a priority at home," he said. "A lot of the teachers knew my home situation. They were the people fighting for me in the corner that I didn't have at home."

He had long been interested in a career in science, but the ACTION program led him to medicine, specifically surgical oncology. The program also convinced Marcum to return to eastern Kentucky after receiving his medical training.

Previously, Marcum had hoped to escape the region due to its lack of job opportunities and educational resources. Now, he believes doing so would be a disservice to the ACTION program and future generations.

"After learning just how bad the [cancer] crisis was and learning that everybody else wants to get out, I can't just leave," Marcum said. "I would rather create an environment for future students to live in Appalachia."

CLINICAL

NCI's Virtual Clinical Trials Office fills the staffing shortages at cancer centers

By Matthew Bin Han Ong

Cancer centers that continue to experience pandemic-induced shortages in staffing their clinical research enterprise may soon be able to rely on support from NCI's Virtual Clinical Trials Office to open studies and accrue patients.

The institute's VCTO, initiated early in 2023 to respond to the alarming loss of workforce in academic oncology during the COVID-19 pandemic, has now provided proof of concept that a team of clinical research associates, nurses, and regulatory affairs personnel—working remotely—can increase screening and accrual at local sites.

The approach appears to be scalable: NCI plans to increase the number of participating sites from six to 30 or 35 lead and affiliate sites within the next two years.

In a previous NCI study based on 2019-2022 trial enrollment data, patient accrual to investigator-initiated and externally peer-reviewed trials were 20-25% below 2019 levels. This decrease was driven by a shift in workforce mobility and preferences during the pandemic: Some clinical trials offices lost up to 50% of their staff, with the majority of clinical research associates moving to higher paying jobs in industry (*The Cancer Letter*, Feb. 17, 2023).

NCI has not updated its survey on CTO staff shortages.

"As we contact sites for potential participation in this pilot, most continue to experience staffing problems leading to backlogs in data reporting, and are eager to join the program," James Doroshow, NCI deputy director of clinical and translational research and director of the institute's Division of Cancer Treatment and Diagnosis, said to The Cancer Letter. *(Slide 1)*

Available data have been presented to cancer center directors at meetings, Doroshow said.

"Routinely after that presentation, people came up to me, 'What can you do? How can you help us? Really, our clinical trials offices are terribly expensive. We can't hire people. We've raised the salaries, still it's difficult finding people to get the work done,'" Doroshow said June 12 at a joint meeting of the National Cancer Advisory Board and the Board of Scientific Advisors.

Accrual to investigator-initiated and externally peer-reviewed trials have not improved in 2023, Doroshow said.

"The accrual data are accurate for calendar year 2023," Doroshow said to *The Cancer Letter*. "It will be several weeks before we can curate the data for the first half of 2024." *(Slide 2)*

Enrollment for these trials in 2023 has not fully recovered to 2019 levels.

"What's important is that we see the dip," Doroshow said at the joint meeting. "But you see that the [National Clinical Trials Network] accrual did come back, pharma accrual did come back. Investigator-initiated trial accrual and grant-supported trials, R01, R21 trials, have not come back.

"As you'll see, continuing to this day, in particular we are facing major problems in terms of having the data management and CRA support to actually keep the trials up to date, in terms of the accrual data getting into the appropriate databases. This continues to be a significant problem." *(Slide 3)*

The VCTO pilot program, which taps into the existing Clinical Research Directorate program at NCI's Frederick National Laboratory for Cancer Research, deploys a team of clinical trials and operations experts to triage institutional needs through study coordination and regulatory support.

"I started thinking about something that may not be clear to those here today," Doroshow said. "And that is that, for many years, part of the activity at the Frederick National Lab, which was funded by the [National Institute of Allergy and Infectious Diseases], was really a program to send CRAs and research nurses to Africa, around the country, for all of the antiviral trials that popped up and had to be activated very quickly in 2020."

After conducting a needs assessment survey of cancer centers and NCI Community Oncology Research Program sites, NCI identified six initial sites for the pilot program in fall 2023—three NCI-designated cancer centers and three NCORP sites that serve rural populations:

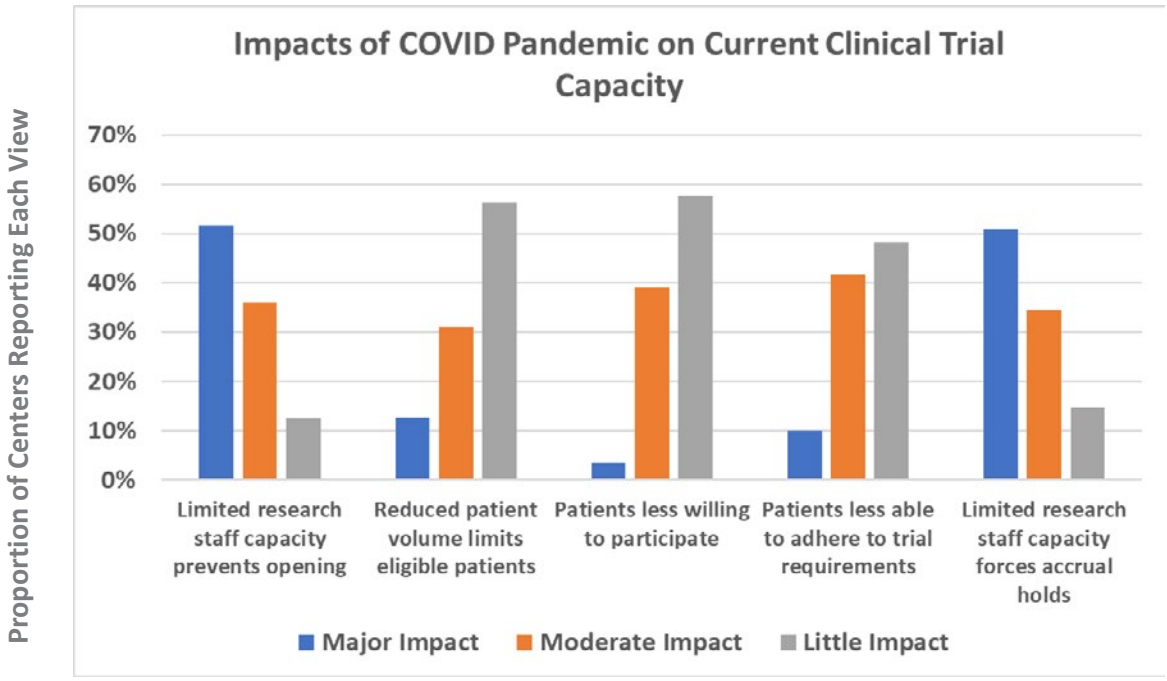
- Montefiore Medical Center, Einstein Campus, Bronx, NY
- University of Texas Mays Cancer Center, San Antonio, TX
- University of Kansas Cancer Center, Kansas City, KS
- Kootenai Clinic Cancer Services, Post Falls, ID
- St. Vincent Hospital Cancer Center, Green Bay, WI
- Geisinger Cancer Institute, PA

How could NCI help?

UT San Antonio, for example, had no staff to screen patients for studies, whereas the NCORP sites in the pilot program needed support with data management, Doroshow said.

"We basically went through a prioritization process, focusing on what institutions made the best case for severe need in the ability to accrue patients from underserved situations," Doroshow said. [We] decided that after having looked at those six institutions, where was the overlap in the clinical trials that they were all performing so we would do a better job of centralizing the support of those activities, but focused on an initial set of 12 or 13 protocols.

"And we've been at it for just over four months. Kansas just came on about a month-and-a-half ago. And I have to



Respondent group for this question: all 64 clinical Cancer Centers

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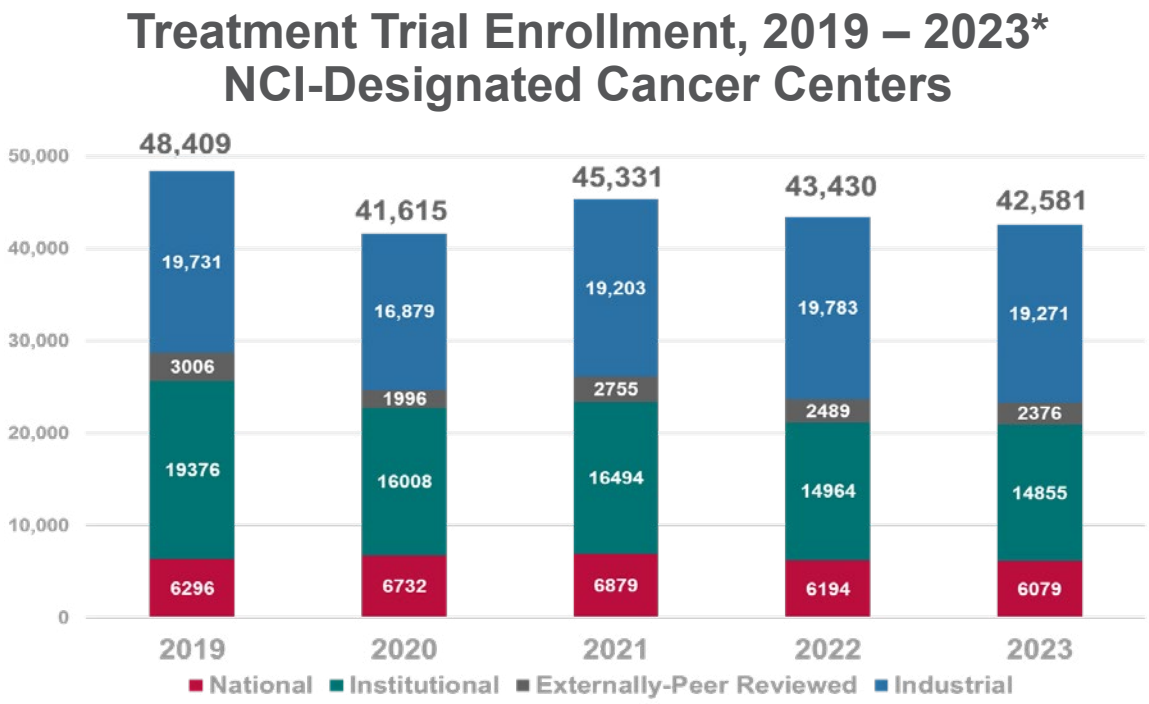

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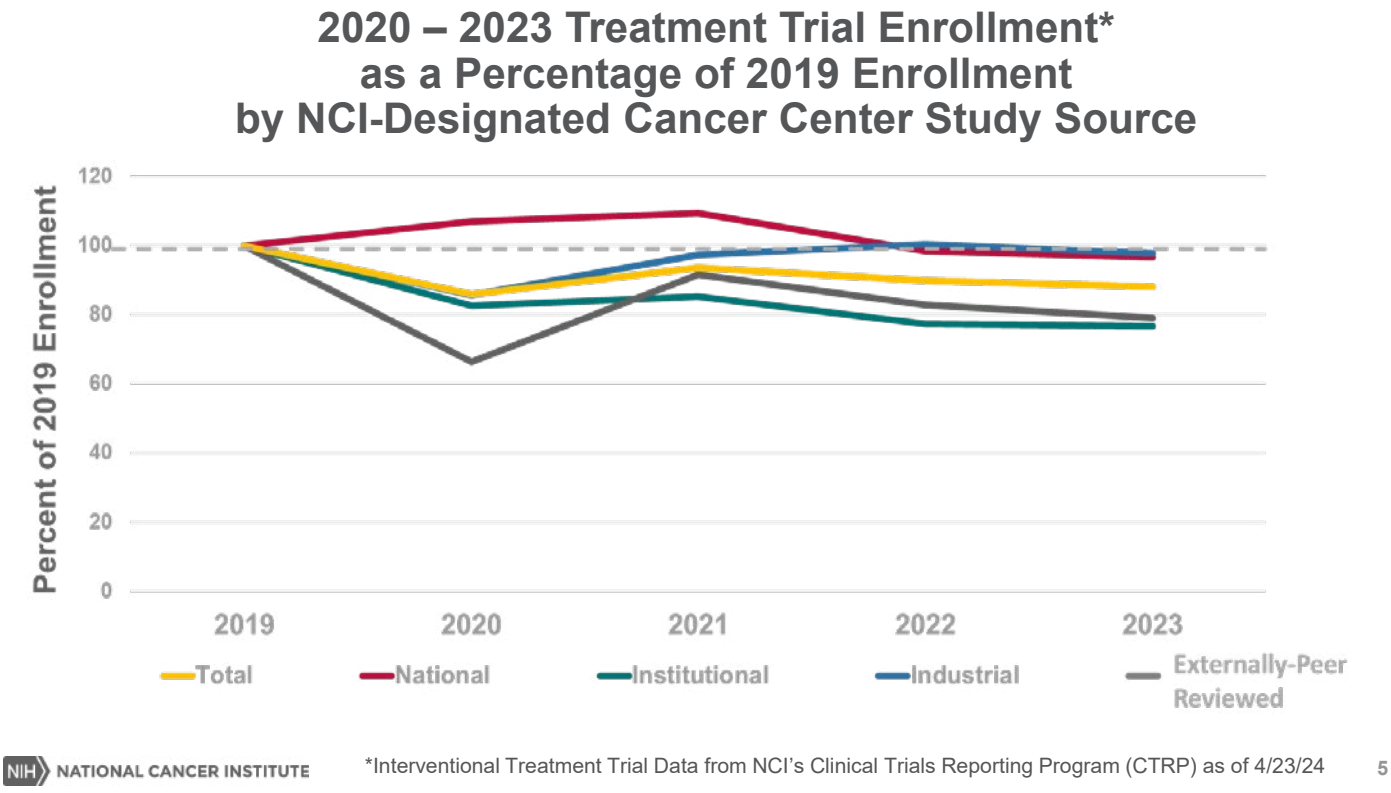
*Interventional Treatment Trial Data from NCI's Clinical Trials Reporting Program (CTRP) as of 4/23/24 4

Slide 2



Slide 3

tell you, I've been overwhelmed by the response."

From December 2023 to April 2024, the NCI VCTO support team was able to screen 4,221 patients, identify 88 eligible patients, and facilitate 24 accruals.

"That's just with three places. The first three," Doroshow said. "Our NCORP sites, we're still … trying to come to a conclusion, get everything set up so that these services can be provided there.

"If we had the resources, [it] would allow us to greatly expand the number of sites that are available where these trials can be undertaken."

NCI is considering adding long-term follow-up services to the offerings in the pilot program. For now, VCTO personnel can provide:

- Eligibility screening and study coordination; promoting trial entry of underserved/rural patients;
- Assistance with informed consent, enrollment, protocol queries, 'help desk' functions
- Data entry/abstraction from EHR to Medidata-RAVE for NCTN, ETCTN, NCORP trials (requiring approval by health provider to access protocol patient data in EHR by remote login);
- Coordinating study visits, procedures, and participant reminders; all to improve retention
- Regulatory support; and
- Adverse event reporting.

NCI's VCTO is, in fact, modeled on an initiative by the Gulf South Clinical Trials Network. The NCORP site used virtual means to provide research support across clinical sites in Louisiana, Mississippi, and Alabama, said Augusto Ochoa, deputy director of the LSU LCMC Health Cancer Center and PI of the network.

"The nascent idea for the Virtual Clinical Trials Office came from when we started our second phase of our NCORP in 2016, 2017," Ochoa said June 12 at the joint NCI advisory meeting. "And as you can see, the NCORP has made a tremendous difference in our corner of the United States where clinical trials had virtually minimal participation prior to 2010. It is well known to this audience that the epicenter of the cancer epidemic is in great part in the Gulf South States, Louisiana, Mississippi, Alabama, and Arkansas.

"And so, about 12, 15 years ago, we started trying to build a coalition of the biggest and most important hospital systems in the state of Louisiana and almost all of the academic centers to form what we now call the Gulf South Clinical Trials Network that is funded now by the NCORP.

"In the sites where it became a routine to have patients enroll on clinical trials

Onboarding Lessons Learned (2)

Slide 4

like our GU site, 68% of our patients went on clinical trials," Ochoa said.

"In summary, over the several years that we've tested this, we've pre-screened about 2,300 patients; we've enrolled about 140," he said.

An excerpt of Doroshow's and Ochoa's June 12 remarks to NCAB and BSA follows:

Doroshow: What have we learned?

Every place is different in terms of getting MOUs set up. Every place is a little bit different in terms of their IT and their IT security, and so you have to learn what the principal questions are at each place. And I think the more we do this, the more we learn what the entire menu of issues are related to IT security.

For all of the people who are going to participate, they have to get the appropriate accounts in the [Clinical Trials Support Unit] to be able to—at both our organization and NCI Frederick, the staff, and also all of the folks at the individual sites—collaborate with respect to the particular trials and the particular accrual. *(Slide 4)*

I think probably the biggest lesson learned, and I don't want to pick on Epic per se—the first six sites that were chosen all are Epic sites—is that this is a big deal, getting accrual and getting access.

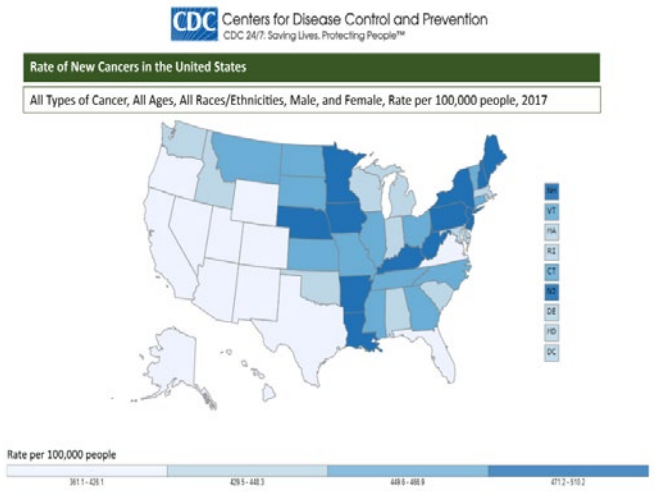
And what I wanted to say is basically what I learned that I was completely ignorant of: I would guess that most of you work at major academic medical centers, and if I were to put it to you and you had to raise your hand, do you think it would be easier to get access to the EHRs at the community sites or at academic medical centers? And I'm willing to bet the vast majority of you would say academic medical centers.

That's wrong.

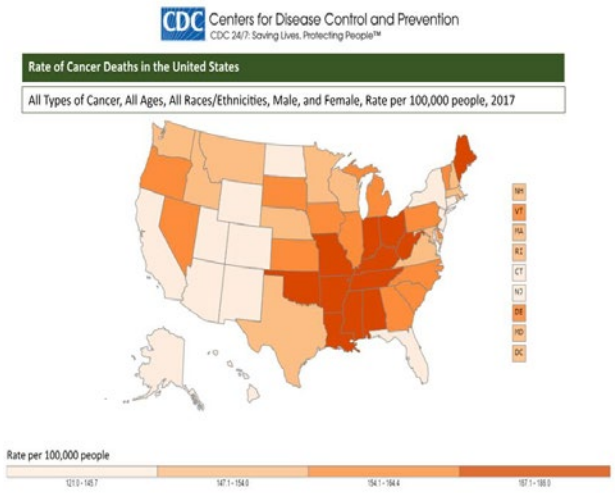
The academic medical centers, actually, own their instance of Epic. It's not that it takes a short period of time, but if the University of Kansas decides that it wants to participate in this activity, then their cancer center director can go to the IT security folks, and it happens. The problem, and something that I had no concept of, is that at many easy-to-deal-with-very-small-practices that own small EHR systems, because they own it, it's for their billing, they want assistance, no problem.

But intermediate hospital systems don't necessarily buy a full instance of Epic or Cerner. In essence, they lease from an intermediary provider these access to these major systems. And so the site may be 100%

Incidence



Mortality



Slide 5

gung-ho to participate; Epic says, "Not our problem." The intermediary though, we have to deal with their lawyers and the IT security issues, and they're really not focused on facilitating clinical research.

That's where our biggest problem has been. That's what I've learned in the last four months. This is really a road. We've learned a lot about how to engage the sites. I think we basically put together materials to try to help individual sites in their clinical trials offices, learn what we need.

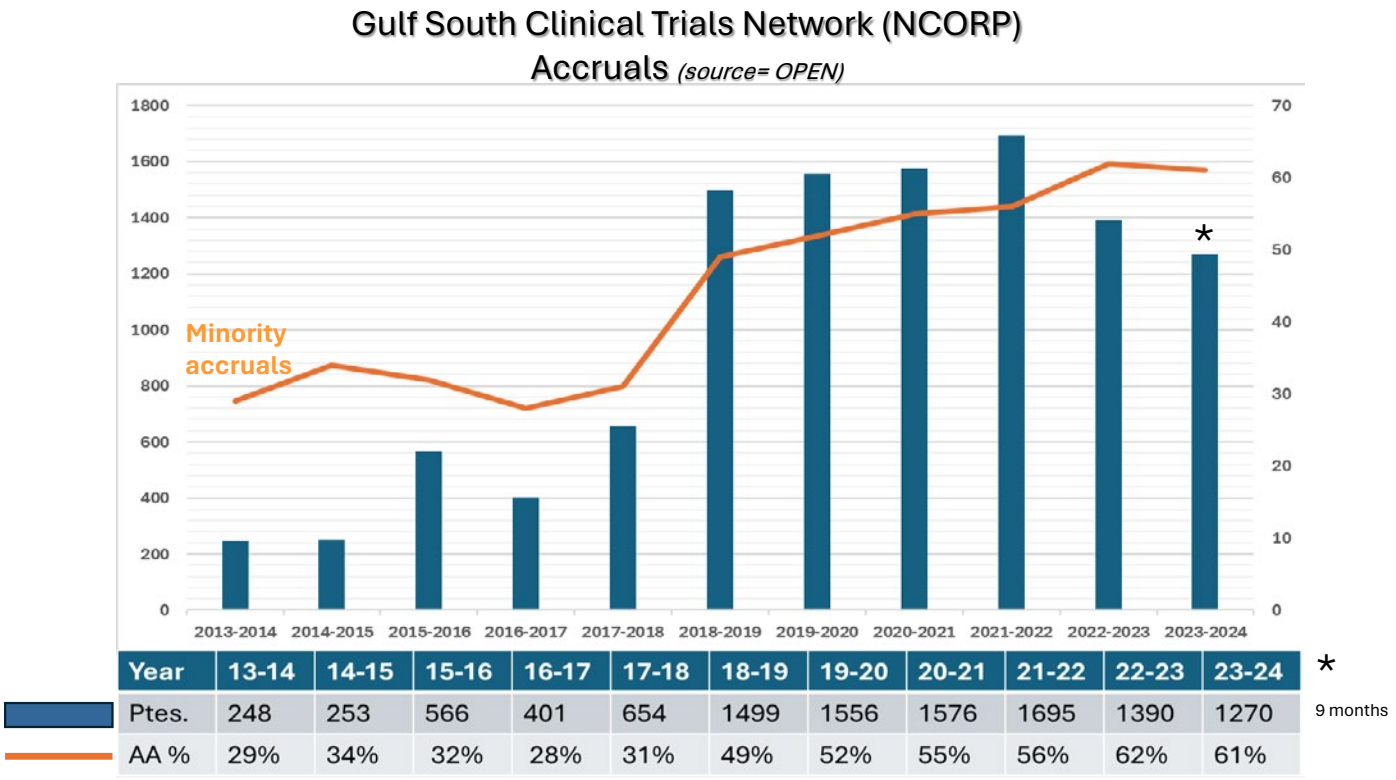
We have a much better understanding of what the legal preparation needs to be able to do this. It really is very safe. You can give single patient access only for the patients on the trials, so that there's really very little chance of data security being breached. But executing the memorandum of understanding, the third-party agreements is time-consuming, but I think will shorten as we've gotten more experience. And we've learned that we need to provide ongoing support for the questions as they arise to help the individual sites move this forward.

Let me just end by talking about future plans. As you saw, we had six initial sites. Those are single sites.

Our push right now is of course every one of these major cancer centers and even the other sites—the Kaiser Clinic, for example, other NCORPs, have multiple other sites, affiliate sites. And so, we're trying to expand to as many of the affiliate sites as possible for the initial six. We have three more lead academic institutions, both NCORP and cancer centers, that we hope to bring on in the very near future. I'm not ready to actually say who those folks are, but ultimately we hope to have about 30, 35 lead and affiliate sites participating within the next two years.

And then, to expand the number of trials that we're supporting to probably 20, 30 trials, and really understand what are the issues: How hard is this? How big of a benefit is this to individuals? And is this really a service that will allow us, once we learn how to do this—because you can easily imagine, it's not just providing assistance at cancer centers that are behind in their data acquisition, as Augusto, I hope, will show you this, might very well allow us to provide services in rural sites and many other places that currently, they just don't have the infrastructure. But if we can provide it for them, which is, I can tell you for sure, this can be done. It is being done.

Really, if we had the resources, [it] would allow us to greatly expand the number of sites that are



Year	13-14	14-15	15-16	16-17	17-18	18-19	19-20	20-21	21-22	22-23	23-24
Ptes.	248	253	566	401	654	1499	1556	1576	1695	1390	1270
AA %	29%	34%	32%	28%	31%	49%	52%	55%	56%	62%	61%

Slide 6

available where these trials can be undertaken.

The last thing I wanted to say is that in conversation with the sites that are actively participating, is that one of the things in addition to that list of services is that they're also very interested in whether or not we could provide access and data for long-term follow up, which I have to admit to you is something that we paid very poorly for, but is absolutely necessary. And so we're trying to consider that.

Let me just go on to introduce Dr. Augusto Ochoa, who really is going to give you hands-on experience with his initial approach to doing this.

Ochoa: Thank you, Jim. And thank you very much for having me here today with you. Again, as Jim was talking about, the nascent idea for the Virtual Clinical Trials Office came from when we started our second phase of our NCORP in 2016, 2017.

And as you can see, the NCORP has made a tremendous difference in our corner of the United States where clinical trials was virtually minimal participation prior to 2010. It is well known to this audience that the epicenter of the cancer epidemic is in great part in the Gulf South States, Louisiana, Mississippi, Alabama, and Arkansas. *(Slide 5)*

And so, about 12, 15 years ago, we started trying to build a coalition of the biggest and most important hospital systems in the state of Louisiana and almost all of the academic centers to form what we now call the Gulf South Clinical Trials Network that is funded now by the NCORP.

This has resulted in us having 49 different clinical sites throughout the region, most of them in the state of Louisiana, but now some in Mississippi and now actually in Alabama. We provide access to clinical trials through all of these sites. And what this has resulted is in a dramatic increase in the number of patients participating in clinical trials.

In 2009, it was somewhere between a hundred to 150 altogether throughout the state of Louisiana. Today, we currently enroll in the last six years, somewhere between 1,200 to 1,500 patients on clinical studies throughout the whole state. And more importantly, as you can see in that yellow line, the participation of minority patients is even more significant.

It has doubled from about 25 to 30% now to routinely enrolling somewhere between 55% and 60% of our

> As we contact sites for potential participation in this pilot, most continue to experience staffing problems leading to backlogs in data reporting, and are eager to join the program.
>
> *– James Doroshow*

patients representing minorities, mostly African Americans. But not everything is happy. *(Slide 6)*

In Louisiana, as we always think of Jazz Fest and all the good things that we do, although our major clinical centers, especially in the academic sites in larger cities in the state of Louisiana, we're enrolling without any problem, the community sites, especially the rural sites, were having a heck of a time enrolling patients.

And so, in our annual meeting in 2017, we asked the physicians, and we asked some of the focus groups that we did with patients, "Why are you not participating? What is the problem? We're giving you everything that we thought you needed." And the answer was, "We'd love to participate." All of them said, "We want to participate," both patients and physicians.

But the physicians said, "We don't have the staff. We cannot afford a research nurse. We cannot afford a data manager, and much less go through all of the regulatory processes."

And the patients said, "We'd love to participate, but we're not going to travel to New Orleans, which is 75 or 80 miles away, or to any of the other cities. Let us do it closer to home."

And we thought at that moment, "This is essential because in Louisiana as in the rest of the country, the majority of patients are treated in community cancer centers, not in our NCI-designated or in large academic centers, so this had to be addressed."

Back at that time, Eileen Mederos, who's the manager of the NCORP and is sitting right here with me, and I started thinking, what can we

VRN Initial Development

Period	Site	Dates	All		White		Black of AA		Other	
			Scr.	Enr.	Scr.	Enr.	Scr.	Enr.	Scr.	Enr.
Preliminary Testing	Lallie Kemp (rural)	6/2017 – 6/2018	170 100%	0	71 42%	0	89 52%	0	1 .05%	0
	LSU GU Oncology (Suburban)	3/2017 – 8/2017	127 100%	26 20%	97 76%	21 81%	22 17%	5 19%	11 9%	0

Scr. = Screened
Enr. = Enrolled

Lallie Kemp: Rural critical access hospital
1 part time oncologist
No research infrastructure
1 trial

LSU GU Oncology: Suburban, associated w community hospital
2 GU Oncologists – academic affiliation
Some research infrastructure
8 trials

Slide 8

do to bring—not telehealth, which traditionally brings the doctor—but through virtual means, bring the research support to these sites. And we started using what was then very mysterious communication systems that we now know have changed completely since COVID. *(Slide 7)*

But at that time we said, "Let's try to see if we can screen the clinics of the doctors ahead of time." We got permission to access the electronic medical records. Our virtual research nurse located in New Orleans would screen the clinics of the doctors ahead of time, would identify patients that were potentially eligible for clinical trials, would discuss those patients with the doctor the week before, and then the doctor would introduce the idea of participating to a clinical trial to that patient when the patient arrived in the clinic.

If the patient said yes, then they would click the computer on, the virtual research nurse would come on. And in some cases, we actually had a little laptop in those places that the virtual research nurse was there all the time. And so then the virtual research nurse would do the consenting, complete all the paperwork needed for enrollment of the patients, set the calendars for all of the activities, and then continue the follow-up.

We tested this initially in two very different sites. One was a small rural hospital with about 100 and some analytic cases, with a part-time oncologist who said they wanted to test this with one trial. The other one was a small academic GU practice that was at a suburban hospital not associated directly with the cancer center. *(Slide 8)*

And what we found out was two things: Number one, we could screen the patients ahead of time. As you can see in both sites, we screened actively. But the only enrollments happened in the site where number one, there was a critical number of clinical trials open.

And number two, where there were full-time physicians that were really committed to this process. At that time, two things happened. Number one, we came to talk to the NCI and we talked to Worta McCaskill-Stevens at that time, who was very enthusiastic about that idea, but said, "Show me that you can do this in more than a couple of places like you've done."

And the second one was we talked with Jim Doroshow, who also endorsed this idea and said the same thing. But the next thing that happened was COVID.

VRN - Pilot Testing

Period	Site	Dates	All		White		Black or AA		Other	
			Scr.	Enr.	Scr.	Enr.	Scr.	Enr.	Scr.	Enr.
Pilot	LSU GU Oncology Clinic (Suburban)	6/2018 – 4/2023	108	73 68%	75 69%	52 48%	22 20%	16 15%	11 10%	5 5%
	Gulfport Memorial Med Onc Group (Rural)	4/2020 – 3/2024	1652	27 2%	1196 72%	18 1.6%	367 23%	9 1%	89 5.3%	0
	West Jefferson Hospital (Suburban)	11/2023 3/2024	278	14 5%	114 41%	10 4%	125 45%	4 1.4%	39 14%	0

LSU GU Oncology: Academic practice – 3 GU oncologists
# of Trials - 17

Gulfport Memorial Med Onc – Rural Community practice – 2 oncologists
# of Trials: from 3 → 16

West Jefferson Hospital – Community
1 - GYN onc ; 1 Med – onc
Trials: from 0 → 10

Slide 9

And when COVID hit, two things were very important. Number one, all of these rules and regulations we had about virtual communications went out the door. Everybody started communicating, everybody started sharing information, and so we did the same. *(Slide 9)*

We continued with our GU oncology group. We opened up another rural site at Gulfport Memorial Hospital in Gulfport, Mississippi, and recently opened a second suburban hospital site. And as you can see here, of all of the patients, we were able clearly to pre-screen the patients, identify those. And in the sites where it became a routine to have patients enroll on clinical trials like our GU site, the first one you see up there, 68% of our patients went on clinical trials.

And the interesting part is that the other suburban hospital also is rapidly ramping up. And the rural hospital has been slowly getting there. And I'll tell you a little bit more about why we think that it is not as rapid as what we'd like. But the other thing that's important is that it really attracted the attention of the physicians at those sites who rapidly increased the number of clinical trials that they wanted to open.

In summary, over the several years that we've tested this, we've prescreened about 2,300 patients; we've enrolled about 140. The VRN can screen an enrolled patient. It has established interest [among] the clinicians for participating in this and has helped us build trust with these rural sites and these community clinics. It also attracted the attention of the federal government. Dr. [Jill] Biden came to visit us and see how this worked.

Lessons learned from what we call the virtual research nurse—[they] can support clinical trials, but as Dr. Doroshow said, each site is different. You have to work very closely with each site. Now, our virtual research nurse meets weekly with our physicians at the different sites, and we meet with them in person quarterly, to review clinical trials, accruals, which trials need to be closed, which trials need to be open. *(Slide 10)*

We also need to get data so we can really refine this process. We're in the process of collecting data through a data plan or research logs, patient engagement surveys and structured interviews that are being led by Denise Danos, one of our public health statisticians.

But I think one of the lessons that I learned very quickly was that the most important help we received

Virtual Research Nurse Screening and Enrollments

Stage	Patients		White		Black of AA		Other	
	Scr	Enr.	Scr.	Enr.	Scr.	Enr.	Scr.	Enr.
Testing	297	26	168	21	111	5	12	0
Pilot	2038	114	1385	80	514	29	139	5
Total	2335	140 6%	1553	101 72%	625	34 24%	151	5 4%

- VRN can screen and enroll patient remotely
- VRN has established interest in clinical trials from community practitioners
- VRN has helped build trust with the academic cancer center

Slide 10

was from being part of the NCORP. All our sites are part of the NCORP. And so, getting user agreements and business associate agreements so that we could access electronic medical records was tremendously much easier than if we were working with unaffiliated sites.

Our next step is to continue the collection of data. The second part was, as I promised Dr. Doroshow back then, that we would write some SOPs so that anybody could take these SOPs and then implement it at their sites according to their needs.

But I think more importantly is what Jim is alluding to. Trying to provide researchers at those sites, or research support or infrastructure at those sites, is almost impossible unless you do it through virtual means.

The research nurses are not going to live in small, rural Louisiana, where they will see a few patients a week or a few patients a month. But they will work locally with us and work with facilitators—we call facilitators—at those sites that will help definitely enroll these patients. And again, I'd like to remind everybody, the majority of our cancer patients are seen and treated at community sites, so we do need to address this issue.

And finally, I just want to thank the people who have really done this work. Dina Brackman, who is actually our lead VRN, Denise Danos, who was our analyst, and some of our other collaborators at these community hospitals that have participated with us. Finally, this was funded by a pilot grant from the NCORP program and from the Al Copeland Foundation, who's our local supporter.

> The nascent idea for the Virtual Clinical Trials Office came from when we started our second phase of our NCORP in 2016, 2017. And as you can see, the NCORP has made a tremendous difference in our corner of the United States.
>
> *– Augusto Ochoa*

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WHITE HOUSE

At White House forum, Bertagnolli, Califf, Wegrzyn call for greater innovation in clinical trials

By McKenzie Prillaman

Leaders of three health agencies presented new initiatives focused on patient-centered research, diversity in clinical trial enrollment, and innovation in clinical research.

The initiatives discussed at the White House Clinical Trials Forum on June 26 included:

- The NIH Communities Advancing Research Equity for Health, abbreviated as CARE for Health,
- The FDA draft guidance for industry titled "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies,"
- The ARPA-H Advanced Analysis for Precision Cancer Therapy, or ADAPT, a program developed as part of the Cancer Moonshot.

Announced earlier this month, Communities Advancing Research Equity for Health is an NIH pilot program that will work with local communities experiencing exceptionally poor health outcomes to figure out which clinical trials would be most meaningful to them.

"We are seeing really bad outcomes, but the bad outcomes are in certain particular segments of our population," NIH Director Monica Bertagnolli said at the White House meeting. "And they are exactly in the segments of our population that don't have access to care and really don't have access to clinical trials."

CARE for Health will support research in primary care practices, and then compile a list of dozens of potential research projects that could be conducted in the community. This allows doctors and patients to choose what research they think would benefit them the most, Bertagnolli said.

"We don't parachute in," Bertagnolli said. "We come for the long duration—we build structure that is enduring, which means we also have to build it within care that is also enduring."

Ultimately, the goal is to form a national primary care research network. NIH is investing about $30 million into CARE for Health over fiscal years 2024 and 2025. Initial awards that will fund organizations serving rural communities are expected to be made this fall.

FDA, too, has been pushing for greater diversity in clinical trials, said Robert Califf, the regulatory agency's commissioner. Although NIH's clinical trials are meeting "first-order" benchmarks in terms of representing sex, race, and ethnicity in the U.S. population, FDA's priorities are a bit different, he said.

"We have a slightly different set of issues because we're regulating a global industry, which obviously has a strong base in the U.S., but most of the 8 billion people in the world don't live in the U.S.," Califf said at the meeting.

To some extent, FDA must persuade industry to include appropriate representation across clinical trial participants, he said.

Califf said the agency's updated draft guidance on "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies," released on June 26, will help sponsors submit Diversity Action Plans to support phase III clinical trials.

"We want people to tell us, 'How are they planning to get the trial done and meet the criteria for engaging and enrolling a diverse group of participants?'" Califf said.

> "We don't parachute in. We come for the long duration—we build structure that is enduring, which means we also have to build it within care that is also enduring."
>
> *– Monica Bertagnolli*

FDA wants to go beyond those "first-order" benchmarks for diversity, Califf said. "There are many other elements of diversity in this country—urban/rural has become a huge factor." Socioeconomic status is another, he said.

"Access to clinical trials is something that everyone should be entitled to. But 90% of what gets introduced into clinical trials that FDA regulates turn out not to make it to market," Califf said. "We have to be very respectful of the people involved, but also make sure they understand what the conditions are—that we're testing something; we don't know how effective it is at this point."

ARPA-H Director Renee Wegrzyn used the recently-launched ADAPT program to illustrate the agency's approach to innovation in clinical research.

Although ARPA-H does not focus on clinical trials, the funding agency does look at how to remove some of the risk for participants, Wegrzyn said. The ADAPT program, launched in March, examines how clinical trials can adapt with participants as their tumors adapt.

"You would think that would be a common practice, but it isn't," Wegrzyn said. "So, breaking what might seem like an intractable problem down into the pieces—the projects we can invest in, make progress against—is really, I think, what we do really well."

ARPA-H's investments are transactional—the agency only funds a research project for its first few years—so the agency does not build relationships through long-term projects, Wegrzyn said. Instead, "we want to build relationships with clinical trials centers, with patient communities, so that we can have almost a leave-behind infrastructure."

"We may work with one center for an osteoarthritis trial, but the next time we work with that center might be for a cancer trial—really planting those seeds to create a rooted network that we can use as an agency well into the future," Wegrzyn said.

OBITUARY

Edward Sondik, electrical engineer turned public health expert and one-time interim NCI director, dies at 82

By Jacquelyn Cobb

Edward Sondik, an electrical engineer by training, followed a career path that led him to top public health positions. He was a director of the National Center for Health Statistics at CDC, an acting director of NCI, and a deputy director of the NCI Division of Cancer Prevention and Control.

Credit for all photos: Centers for Disease Control and Prevention, National Center for Health Statistics

Sondik died on June 25 after a brief illness. He was 82.

How does an electrical engineer become a public health leader at NCI and the CDC? In an oral history conducted by the NCI Division of Cancer Prevention Oral History Project in 2009, Sondik attributed his career direction to his graduate research focus on operations research and management science.

"I did my graduate work on the side of electrical engineering that doesn't deal with resistors, wires, capacitors, and so forth, but is really on the control side, control system side, and it's—actually was closer to operations research—or management science, really," Sondik said.

Initially, he worked at what was then called the National Heart and Lung Institute.

"Around my fifth or [sixth] year, I heard that NCI was starting a biometrics and operations research branch."

Sondik thought his expertise was the right fit for the fledgling division, back in 1990 (*The Cancer Letter*, Sept. 7, 1990).

"There was, of course, focus on the usual analytic sciences, epidemiology, demography and mammography to a degree. But I said, 'Operations research is focused on decisionmaking.' And I said, 'That's really quite crucial to health policy,'" Sondik said. "I said, 'Well, whoever is talking about operations research at NIH is my kind of person,' because there was no activity like that at that point at NIH."

That person was Peter Greenwald, founding director of the Division Cancer Prevention and Control, now separated into the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences.

"Peter Greenwald's office, it turns out, was one floor, literally one floor below where I was located," Sondik said. "I was on the fifth floor in Building 31A, and he was on the fourth floor in Building 31A. So, I went down and talked to him, and came to be the head of that new branch."

> "Ed was a mentor to many, including me. He was a very disciplined, wise, quiet soul who supported many young scientists. Ed was very supportive of me, and wrote the letter that led to me receiving tenure at the NCI. I, like many, truly felt his support."
>
> *– Otis Brawley*

Greenwald remembers Sondik's appearance in the office on the fourth floor.

"He came down right at an optimal time, and it was just what we needed, which was someone who really understood the various approaches to human clinical trials and also epidemiological approaches to studying cancer in people," Greenwald said to *The Cancer Letter*. "He was a bit on the modest side—that is, he would wait and listen carefully, and he was very good at integrating the thoughts of the various participants and coming up with a succinct statement and understanding of what it was we were driving at. Then he helped improve upon the quality and the efficiency of the research we were doing.

"Edward Sondik was a wonderful scientist and friend," Greenwald said. "He was highly respected by everyone at the National Cancer Institute when he was there as the deputy director of the Division of Cancer Prevention and Control, all of us will miss him."

After Sondik left NCI for the National Center for Health Statistics, Barry Kramer filled the role of deputy director of Cancer Prevention and Control.

"I assumed his position after he left, which was an honor to me because he had big shoes to fill, and I thought that it was a highlight in my career that I would even be considered to take his position after he left."

Kramer described Sondik as "someone everyone looked up to."

"The best way of describing him—and I did have the privilege of working directly for him—is that he was really a true gentleman." Kramer said to *The Cancer Letter*. "I think he was admired and loved by all of his staff and colleagues, but he also brought to the division of Cancer Prevention, a real careful, rigorous science, and he brought a very meticulous approach to analysis of cancer statistics and interpretation of cancer statistics.

"I also viewed him as just an outstanding advisor in my career as I was coming up, I was junior to him, and I think it was a game national for the National Center for Health Statistics, that he took a position heading NCHS there, but it was at the same time, a loss to the Division of Cancer Prevention."

Sondik became the NCI acting director upon resignation of Samuel Broder (*The Cancer Letter*, Dec. 22, 1994; Jan. 27, 1995). Previously, Sondik had served as acting deputy director of NCI after Daniel

Sondik at the 2010 National Conference on Health Statistics

Ihde left the institute (*The Cancer Letter*, March 4, 1994).

Sondik served as the NCI acting director for six months.

"He was, for a time, acting director of the National Cancer Institute, and he brought a steady hand at a difficult time," Kramer said. "It was a time when fraud had been discovered in the oncology community, and he had such a level head. He was cool-headed, and so he was just the right person at the right time during that period of the National Cancer Institute.

"I thought he was the right man for every job that he held, although I was sorry to see him go to NCHS."

Sondik left a lasting impression on those he worked with, Kramer said.

"No matter who you call, you're going to hear nothing but an outpouring of love for Ed. He was just quite a good person. Just a good person," Kramer said.

Otis Brawley, the Bloomberg Distinguished Professor of Oncology and Epidemiology at the Johns Hopkins University Sidney Kimmel Comprehensive Cancer Center, is one of Sondik's many mentees.

"Ed Sondik was an engineer who led the National Cancer Program by applying engineering principles," Brawley said to *The Cancer Letter*. "As acting director, he successfully led the NCI through turbulent times.

"Ed was a mentor to many, including me. He was a very disciplined, wise, quiet soul who supported many young scientists. Ed was very supportive of me, and wrote the letter that led to me receiving tenure at the NCI. I, like many, truly felt his support."

Sondik is survived by his wife of 60 years, Elinor; son and daughter-in-law Robert and Joanna; daughter and son-in-law Karen and Seth; four grandchildren, Max, Adam, Noah, and Jacob; and sisters and brothers-in-law, Arlene and Dan Neiditz and Sheila Sondik and Paul Sarvasy.

BSA approves five new, 17 reissue concepts

By McKenzie Prillaman

The NCI Board of Scientific Advisors approved five new concepts and 17 reissue concepts at a joint meeting of the BSA and the National Cancer Advisory Board June 11-12.

At the meeting, NCI Director Kimryn Rathmell said that after a year of lean appropriations, the institute is facing what threatens to be a budgetary cataclysm—a potential 10-11% cut to the Labor-HHS spending bill in fiscal year 2025 (*The Cancer Letter*, June 14, 2024).

"As you can see, our gap is just getting bigger, and so, we are spending a lot of time thinking about efficiencies, really thinking about what we can do with the funding that we have, because we have a big mission and we have real work to do to end cancer as we know it," Rathmell said at the meeting.

Presentation slides for the approved BSA concepts are available on the NCI website.

The Confluence of Cancer and HIV Stigma in HIV-Positive Individuals Diagnosed with Cancer (RFA)

The goals of the RFA are to expand current understanding of the confluence of cancer stigma and HIV stigma among people with both diseases, assess the impact of these two converging stigmas on cancer outcomes among people with HIV and cancer, leverage stigma reduction interventions at multiple levels to intervene on modifiable mechanisms of stigma that contribute to negative cancer outcomes, and promote research in diverse domestic and international contexts, focusing on regions where the HIV-cancer burden is elevated.

This RFA was submitted by the Division of Cancer Control and Population Sciences, Center for Global Health, Center to Reduce Cancer Health Disparities, and the Office of HIV and AIDS Malignancies.

The total requested budget will be up to $6 million per year starting in FY2025. Five to six R01 grantees will be awarded. The project period is for five years, with up to $600,000 per year. Additionally, three R21 grants of two years with a total budget of up to $275,000 will be awarded.

Example research topics responsive to this RFA include:

- Assessment: Longitudinal studies to assess the impact of cancer stigma and HIV stigma on cancer outcomes among PWH with cancer,
- Investigational: Studies that investigate factors that exacerbate or mitigate association of cancer stigma and HIV stigma with cancer outcomes,
- Interventional: Stigma reduction interventions implemented at individual, provider, community, and/or structural levels to improve cancer outcomes in PWH with cancer.

Two dedicated RFAs would:

- Demonstrate NCI's commitment to this high-priority research area and incentivize submission of applications,
- Support a bolus of transdisciplinary research projects led by domestic and international investigative teams, and
- Require special referral considerations and an NCI Special Emphasis Panel.

Scaling-up and Maintaining Evidence-based Interventions to Maximize Impact on Cancer (SUMMIT) (RFA)

The purpose of SUMMIT is to increase the wide-scale, long-term delivery of effective cancer-related interventions, reduce cancer-related deaths by significantly increasing lung cancer screening among populations at high risk for the disease and tobacco use treatment services among cancer survivors, and develop generalizable knowledge on how to scale up and sustain effective cancer-related interventions.

This RFA was submitted by the Division of Cancer Control and Population Sciences.

The proposed budget for FY25-30 is $42.2 million. Six UG3 grantees will be awarded $800,000 per year for FY25-26, totaling $9.6 million. This amount includes anticipated support from Moonshot funds. Six UH3 grantees will be awarded $1.36 million per year for FY27-30, totaling $32.6 million. Not all projects may progress from UG3 to UH3 phase.

Proposed mechanism:

- UG3: Planning–Exploratory Phase
  - Two years
  - Finalize scale-up and sustainment trial components
  - Refine scale-up and sustainment strategies
- NCI Administrative Review
  - Review and evaluate UG3 milestones
  - Assess probability of completion of UH3
  - Approve/reject transition request
- UH3: Implementation Phase
  - Four years

- Conduct scale up and sustainment trial

Evaluation criteria:

- Short Term (UG3 Phase, Years 1-2):
  - Completion of all trial preparatory activities
  - Refinement of scale-up and sustainment strategies
  - Engagement in collaborative SUMMIT activities
  - Achievement of UG3 milestones
- Long Term (UH3 Phase, Years 3-6):
  - Empirical evidence on how to best scale-up and sustain interventions
  - Significant increase in LCS for populations at high-risk for lung cancer and smoking cessation among cancer survivor populations
  - Cross-learning and collaboration in SUMMIT activities
  - Practical tools and public goods to support scale-up and sustainment

Example study:

- Design: Cluster randomized controlled trial with 100 Federally Qualified Health Center clinics
- Methods: Test comparative effectiveness of two system-level strategies to scale up and sustain LCS
  - Practice facilitation and innovative financing vs. Learning collaborative model
- Outcomes: System-level guideline concordant care of LCS measured at 12, 18, and 24 months

Social Determinants of Health and Quality of Care Contributors to Cancer Disparities in People with HIV (RFA/Coop. Agr.)

The purpose of this RFA is to increase NCI's research portfolio investigating cancer disparities in people with HIV and advance the understanding of which SDoH are important and how they intersect with cancer care inequities to contribute to disparities in the prevention, diagnosis, and treatment outcomes of PWH and cancer, with an expectation that the research may inform future interventions.

This RFA was submitted by the Office of HIV and AIDS Malignancy and Center to Reduce Cancer Health Disparities, in collaboration with the Division of Cancer Control and Population Sciences, Division of Cancer Prevention, and Division of Cancer Treatment and Diagnosis.

The requested budget will be $15 million for three years starting in FY25, totaling $45 million. Three receipts are requested in FY25-FY27. For each receipt date, three to four U01 grantees will be awarded, for up to 12 total. They will receive $3 million each fiscal year.

Research scope:

- Research to better understand how multiple SDoH interact and contribute to health disparities in cancer prevention, diagnosis, treatment and outcomes in PWH
- Research eliciting how provider-level and system-level factors influence the quality of cancer care to PWH
- Research identifying and testing strategies to alleviate SDoH that affect PWH receiving quality care, including enrolling in clinical trials, cancer screenings, etc.

RFA management logistics:

- NCI-wide team, led by OHAM and CRCHD, will co-manage the RFA
  - Determine responsiveness and referral
  - Prepare funding plan
  - Conduct evaluation
- Applications will be referred across NCI DOCs according to DEA referral guidelines
- A U01 mechanism is proposed:
  - Allow Program Staff to facilitate regional/institutional collaborations between HIV and Cancer fields
  - Annual Principal Investigators' Meeting: Foster dissemination of information, discuss challenges, and identify opportunities for collaboration

Previous efforts that informed this concept:

- FY23: Administrative Supplements to P30 Cancer Center Support Grants
  - 11 applications received; 6 awards made
  - Purpose: Develop interdisciplinary teams, establish research infrastructure, and support exploratory projects seeking to understand the role of SDoH and cancer care inequities in leading to cancer disparities in PWH. Encouraged collaborative efforts between Cancer Centers and Centers for AIDS Research (CFARs)
- FY23-FY24: Basic/Translational Research on Health Disparities in

Underrepresented People Living with HIV (PLWH) and Cancer

- RFA-CA-22-056 (R01)
- RFA-CA-22-057 (R21)
- Purpose: Investigate biological interactions of cancer disparities in PWH from underrepresented groups to understand how HIV promotes disparities in cancer 6 initiation, progression, and the resulting pathogenic disease sequelae.

The NCI Pathway to Independence Award (K99/R00) (PAR)

The objective is to help outstanding postdoctoral researchers complete needed, mentored career development and transition in a timely manner to independent, tenure-track, or equivalent faculty positions. But the four-year eligibility limit is a major hurdle for some applicants.

Submitted by the Center for Cancer Training, the proposed NCI K00/R00 PAR will expand the eligibility window for applicants to six years of postdoctoral research experience, increasing inclusivity of the award. Additionally, the CCT K22 program would end, folding its budget into the new K99/R00 PAR, and eliminating a mechanism with an eight-year eligibility window, citizenship restrictions, and that is difficult to maintain from a budgetary standpoint.

The total anticipated cost of the R00 phase is $25.5 million, starting in FY28.

An overview of proposed NCI K99/R00 PAR follows:

- Postdoc experience: Up to six years
- Citizen requirements: None
- Award duration (max.): five years
- Mentored support: two years
- Independent support: three years
- Estimated number of applications: 300
- Estimated total costs/year: $9.9 million

Tobacco, Alcohol, and Cannabis Control Policy Research for Health Equity (Clinical Trial Optional) (PAR)

This PAR's goal is to support R01 and R21 research projects that focus on reducing disparities in tobacco, alcohol, and/or cannabis exposure or use by evaluating new or adapted policies pertaining to tobacco, alcohol, and/or cannabis in the U.S.

Submitted by the Division of Cancer Control and Population Sciences, the PAR aims to explore whether policies promote health equity and reduce health disparities, or if there are unanticipated effects that worsen health disparities. Further, policy aimed at one substance may affect other substances through co-use or substitution.

No budget cap for projects under this PAR was specified.

FY2025 NCI SBIR contract topics (RFP)

The NCI Small Business Innovation Research program supports grants and contracts.

As part of the FY25 selection process, SBIR presented contract topics to the BSA.

Novel Delivery Systems for RNA-based Cancer Vaccines

Goal: Support the development of new delivery systems with enhanced properties to accelerate the development of RNA-based cancer vaccines.

- Center for Strategic Scientific Initiatives

Development of Cancer Immunoprevention Agents

Goal: Advance the development of novel, safe, and efficacious immunopreventive vaccines (DNA, mRNA, peptide) or immunomodulatory drugs (small molecules or biologics) for cancer prevention and interception in well-identified high-risk cohorts (e.g., Lynch syndrome, BRCA, FAP, smokers, asbestos exposed, precancers such as PanIN, IPMN, STIC, PIN, CIN, adenoma, Barrett's esophagus).

- Division of Cancer Prevention
- Division of Cancer Biology

Synthetic Microbes (Excluding Oncolytic Viruses) for Immuno-Oncology Therapies

Goal: Support the development of safe and effective immune-modulating synthetic microbes for immuno-oncology (IO) therapeutic use in the clinic.

- Division of Cancer Treatment and Diagnosis

Development of Novel Therapeutics for HPV-related Precancer

Goal: Develop effective HPV therapeutics that can treat chronic HPV infections and/or cause regression of precancers by preventing HPV-related cancers from developing at relevant organ sites (e.g., cervical, anogenital, oropharyngeal).

- Division of Cancer Prevention

Precision Nutrition Interventions to Reduce Cancer-Related Symptoms

Goal: Support the development of new targeted nutritional products for patients experiencing nutrition impact symptoms to help clinical care teams maintain patient's nutritional status, quality of life, and bolster a patient's tolerance for cancer treatment.

- Division of Cancer Prevention
- Division of Cancer Control and Population Sciences

Drug-Loaded Carrier Particles for Improved Oral Delivery for Colon Cancer Prevention

Goal: Develop oral preventative agents for high-risk patients with Inflammatory Bowel Disease (IBD) to prevent colon cancer.

- Division of Cancer Prevention

Antibody-Drug Conjugates as Radiopharmaceutical Theranostics for Cancer

Goal: Improve efficacy of ADCs by labeling them with radionuclides and for a new theranostic treatment strategy that includes diagnostic, imaging-based patient selection followed by two-armed therapy (chemical- and radiation-based).

- Division of Cancer Treatment and Diagnosis

Point of Care Detection of Antibodies Against HPV16/18 E6 and E7 Oncoproteins

Goal: Support the development and validation of a rapid, point of care (POC) test for Human Papillomavirus (HPV)-related oropharyngeal cancers that includes the separate detection of antibodies against HPV16 and 18 E6 and E7 proteins.

- Division of Cancer Prevention

Point of Care Technologies for GI Cancer Prevention and Early Detection

Goal: Advance the development of an affordable and scalable point of care (POC) test that can effectively screen for precancerous conditions and early cancers in the gastrointestinal (GI) tract (esophagus, stomach, small and large intestine, rectum, anus).

- Center for Global Health
- Division of Cancer Prevention
- Division of Cancer Control and Population Sciences

Development of Digital Biomarkers and Endpoints for Clinical Cancer Care

Goal: Facilitate the commercial development of digital biomarkers and/or endpoints that can help clinical care teams improve patient care (e.g., remote monitoring of a patient's response to treatment). Digital biomarkers will utilize data from digital health technologies (e.g., heart rate, oxygen saturation, sleep, physical activity, etc.) and demonstrate clinical utility for patients.

- Division of Cancer Control and Population Sciences
- Division of Cancer Treatment and Diagnosis
- Center for Strategic Scientific Initiatives

Digital Twin Software for Optimization of Cancer Radiation Therapy

Goal: Development digital twin software that can inform radiation therapy in patient care by utilizing multi-scale data (e.g., molecular, cellular, organ, organism, societal, geographic, modalities available, family history, cost and toxicity) for treatment optimization purposes.

- Division of Cancer Treatment and Diagnosis

Wearable Technologies to Facilitate Remote Monitoring of Cancer Patients Following Treatment

Goal: Facilitate the commercial development of wearable sensors that can provide remote patient monitoring and assist clinical care teams in identifying cancer treatment-related toxicities early on.

- Center for Strategic Scientific Initiatives
- Division of Cancer Treatment and Diagnosis

Advanced Biomaterials to Improve Cancer Modeling for Research

Goal: Advance the development of versatile and accessible biomaterial-based tools (kits and reagents) for cancer researchers. Biomaterials should be able to change or adapt in response to tumor initiation, progression, or metastasis (e.g., adaptable response to tumor, changes in stiffness, strain or cross-linking, etc.).

- Division of Cancer Biology

PAR reissue concepts

The Division of Extramural Activities submitted 17 reissue concepts and 28 notice of funding opportunities that were approved:

- NCI Mentored Clinical Scientist Research Career Development Award to Promote Diversity (K08 Clinical Trial Required)

- NCI Mentored Clinical Scientist Research Career Development Award to Promote Diversity (K08 - Independent Clinical Trial Not Allowed)
- NCI Mentored Research Scientist Development Award to Promote Diversity (K01 Independent Clinical Trial Not Allowed)
- NCI Mentored Research Scientist Development Award to Promote Diversity (K01 Clinical Trial Required)
- NCI Transition Career Development Award to Promote Diversity (K22 Independent Clinical Trial Not Allowed)
- NCI Transition Career Development Award to Promote Diversity (K22 Clinical Trial Required)
- Basic Research in Cancer Health Disparities (R01 Clinical Trial Not Allowed)
- Basic Research in Cancer Health Disparities (R21 Clinical Trial Not Allowed)
- Basic Research in Cancer Health Disparities (R03 Clinical Trial Not Allowed)
- The Metastasis Research Network (MetNet): MetNet Research Projects (U01 Clinical Trial Not Allowed)
- Dissemination and Implementation Research in Health (R01 Clinical Trial Optional)
- Dissemination and Implementation Research in Health (R21 Clinical Trial Optional)
- Dissemination and Implementation Research in Health (R03 Clinical Trial Not Allowed)
- Cancer Epidemiology Cohorts: Building the Next Generation of Research Cohorts (U01 Clinical Trial Not Allowed)
- Research Opportunities in Established Cancer Epidemiology Cohort Studies (U01 Clinical Trial Not Allowed)
- Clinical Characterization of Cancer Therapyinduced Adverse Sequelae and Mechanism-based Interventional Strategies (R01 Clinical Trial Optional)
- Mechanisms that Impact Cancer Risk after Bariatric Surgery (R01 Clinical Trial Optional)
- Mechanisms that Impact Cancer Risk after Bariatric Surgery (R21 Clinical Trial Optional)
- Cancer Prevention and Control Clinical Trials Planning Grant Program (R34 Clinical Trials Optional)
- Cancer Prevention and Control Clinical Trials Planning Grant Program (U34 Clinical Trials Optional)
- Utilizing the PLCO Biospecimens Resource to Bridge Gaps in Cancer Etiology and Early Detection Research (U01 Clinical Trial Not Allowed)
- Toward Translation of Nanotechnology Cancer Interventions (TTNCI) (R01 Clinical Trial Not Allowed)
- Molecular Imaging of Inflammation in Cancer (R01 Clinical Trial Not Allowed)
- Integration of Imaging and Fluid-Based Tumor Monitoring in Cancer Therapy (R01 Clinical Trial Optional)
- Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21 Clinical Trial Not Allowed)
- Exploratory/Developmental Bioengineering Research Grants (EBRG) (R21 Clinical Trial Optional)
- Integrating Biospecimen Science Approaches into Clinical Assay Development (U01 Clinical Trial Not Allowed)
- Cancer Center Support Grant (CCSG) (P30 Clinical Trial Optional)

Robert Uzzo, MD, MBA, FACS
President and CEO, Fox Chase Cancer Center

Jonathan Chernoff, MD, PhD
Director, Fox Chase Cancer Center

WE DISCOVER. WE DELIVER.™

Fox Chase Cancer Center has paved the way since the early 20th century in making innovative discoveries that deliver better cancer care. We are now celebrating a tremendous 50 years since American Oncologic Hospital and the Institute for Cancer Research united in 1974 to create what we know today as Fox Chase – as well as the prestigious honor of our very first NCI designation as a Comprehensive Cancer Center that same year.

Throughout our history, Fox Chase has built a proud legacy in research, prevention and care, with a singular focus on advancing our understanding of cancer for the benefit of our patients. From the discovery of the Philadelphia Chromosome and the identification of the hepatitis B virus to our role in transforming biomedical research and bringing forward groundbreaking treatments, our researchers and clinicians are internationally recognized for their vast expertise in reducing the burden of cancer.

Our collaborative spirit, our culture of innovation, and our dedication to culturally competent care for our diverse patient populations drive our momentum for the future. At Fox Chase Cancer Center, where the brightest minds come together to create better medicine, we are making a difference every day in our collective goal to prevail over cancer.

foxchase.org/discovery

Fox Chase Cancer Center
Temple Health

IN THE ARCHIVES

CANCER HISTORY PROJECT

Edward Sondik on his beginnings in public health, cancer prevention, and a "battlefield promotion"

Edward Sondik, former director of the National Center for Health Statistics at CDC, who previously served as an acting director of NCI, and a deputy director of the NCI Division of Cancer Prevention and Control, died on June 25. He was 82.

An obituary appears on page 24.

Sondik brought his operations and management expertise to the nascent Division of Prevention and Control at NCI.

In an oral history conducted by the NCI Division of Cancer Prevention Oral History Project in 2009, Sondik chronicles his journey from deputy director of the Division of Prevention and Control to acting director of NCI.

Said Sondik:

> I got kind of a battlefield promotion when Sam Broder was director and I became the NCI Acting Deputy Director. The then-current Deputy Director had unexpectedly died.
>
> An acting deputy director for NCI was needed. So, Broder came down from the eleventh floor to the tenth floor, walked in on me one day and said, "How would you like to be the acting deputy director?"
>
> I was completely floored. So, as they say, it seemed like a good idea at the time, so I said Yes.
>
> We briefly thereafter encountered a scandal related to breast cancer treatment...There were accusations that, in one of the large cooperative groups that conducted cancer treatment trials for breast cancer, one of the many, many investigators had falsified data. And the person who headed the overall group was an icon named Bernie Fisher.
>
> And to make a long story short, there was a Congressional investigation and the agency became just almost paralyzed by this.
>
> As this was coming to a close, Sam Broder left. I then became the acting director of NCI for a period of about, I don't know, six or eight months.

Read the full transcript on the Cancer History Project:

Division of Cancer Prevention Oral History Project Interview with Edward Sondik
By National Cancer Institute, June 28, 2024

> Conducted on January 9, 2009, by Philip L. Cantelon, History Associates Inc.
>
> At the time of this interview, Dr. Edward Sondik served as the Director of the National Cancer Center for Health Statistics (NCCHS) of the Center for Disease Control and Prevention.
>
> This interview covers Dr. Sondik's early work with the Division of Cancer Prevention and Control and the growth of epidemiology. He discusses the pioneering aspects of the division and the development of the

Cancer Surveillance Program and the Surveillance, Epidemiology and End Results (SEER) Program. While working for the DCP and the NCI, Dr. Sondik assumed administrative roles and his work often concerned policy and coordination between NCI, the NIH, and even Congress. This interview reflects his transition from SEER director to influential administrator.

Related articles

NCI's Goal To Increase Minority Participation In Trials, Sondik Says
By The Cancer Letter, May 5, 1995

NCI is committed to increasing the participation of minorities in clinical trials, the Institute's acting director said last week.

Edward Sondik, speaking at a symposium on minorities and cancer held in Washington last week, said cancer researchers have had only limited success in involving more minorities in their studies.

"We are having difficulties recruiting minorities to these trials," Sondik said. "We have tried mightily."

NCI Is On "Path To Stability," Sondik Tells House Committee
By The Cancer Letter, April 7, 1995

Having weathered several years ofturmoil, NCI remains a solid institution, the Institute's Acting Director Edward Sondik said at a Congressional hearing last week.

"I won't say that all has been easy over the last few years, but I do feel that we are on a very good path toward stability, and I think the mental health of the place is pretty good at this point," Sondik said at a hearing ofthe House Appropriations Subcommittee on Labor, HHS & Education.

> "Treatment was a research colossus with the cooperative groups having been set up with a huge amount of infrastructure. And there was also a lot of infrastructure associated with epidemiology in another division. I think people (other NCI staff) were really encouraging, but I don't know that prevention and control had as much respect as it really should."
>
> *– Edward Sondik, 2009*

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. You can also follow us on Twitter at @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.

IN BRIEF

MD Anderson, Rice form Cancer Bioengineering Collaborative

The University of Texas MD Anderson Cancer Center and Rice University formed the Cancer Bioengineering Collaborative to develop innovative technologies and bioengineering approaches to improve cancer research, diagnosis, and treatment.

Led by Rice's Gang Bao and MD Anderson's Jeffrey Molldrem, the initiative aims to foster collaboration between the two institutions on fundamental and translational cancer research, to develop technologies for cancer detection and therapy, and to secure external funding in support of further research and training.

Envisioned as a hub for accelerating the pipeline from laboratory research to clinical application, the Cancer Bioengineering Collaborative leverages the two institutions' complementary strengths to drive discovery and innovation in five key research areas:

- Cell therapies: Developing more effective cell-based immunotherapies, including chimeric antigen receptor- and T cell receptor-based approaches,
- Nanotechnologies: Using nanoparticles for targeted cancer detection and therapy,
- Cancer vaccines: Incorporating advanced biomaterials, synthetic biology, and nanoparticle delivery systems to develop therapeutic cancer vaccines,
- Artificial intelligence: Leveraging advanced computing tools for high-precision analysis of samples to identify targets and inform therapeutic design,
- Molecular imaging: Deploying advanced molecular imaging techniques to enhance diagnostic and therapeutic tools.

In support of its goals, the collaborative will launch new joint efforts, including a seed grant program to facilitate collaboration between investigators at Rice and MD Anderson; a monthly seminar series focused on cancer bioengineering; annual retreats to showcase cutting-edge research and further stimulate new collaborations; and hosting international leaders in cancer and bioengineering research.

If you like big houses and have $34.9M to spend, ACS has a house for you

The American Cancer Society is selling the 25,000 square-foot mansion that was donated to the society by former Washington Commanders owner Dan Snyder and his wife Tanya Snyder, a breast cancer survivor, in March (*The Cancer Letter*, March 29, 2024).

The Snyder estate, now being sold by ACS. Source: Google, ©2024 Airbus

According to the listing, the four-story house in Potomac, MD, is sited on 13.5 acres, and has commanding views of the Potomac River.

ACS's asking price is $34.9 million.

Vivek Kavadi named CEO of American Society for Radiation Oncology

Vivek S. Kavadi was named CEO of the American Society for Radiation Oncology. He will succeed Laura Thevenot, who has led the organization since 2002.

Kavadi will start on Nov. 1.

Kavadi, a radiation oncologist and ASTRO member since 1994, is currently chief

radiation oncology officer for the U.S. Oncology Network, where he oversees strategy, operations, and clinical service delivery for a network of 200 physicians.

From 2003 to 2020, Kavadi was regional medical director for Texas Oncology, where he managed a 60-physician practice in the Houston region. Since 1995, Kavadi also has maintained a clinical practice as a radiation oncologist for Texas Oncology, where he specializes in breast and prostate cancers.

Kavadi's history with ASTRO includes his current role on the board of directors as vice chair of the Health Policy Council, and his previous tenures on the Health Policy and Payer Relations Committees. In 2019, he was recognized by ASTRO as a fellow for his service to the society and his contributions to the field of radiation oncology.

"I do not take the challenge of leaving my current role in community cancer care to lead a national organization lightly," Kavadi said in a statement. "I recognize that I will step into the role succeeding Laura Thevenot, who has led the organization with skill and distinction for the past 22 years.

"I know I will be at the helm of a healthy, thriving organization, and I am committed to fostering further collaboration, scientific advancement, and excellence within our specialty."

Miguel Villalona Calero named deputy director of UC Irvine Chao Family CCC

Miguel Villalona Calero was named deputy director of the University of California, Irvine Chao Family Comprehensive Cancer Center and division chief for hematology/oncology. He will start on July 8.

He joins the CFCCC from City of Hope National Medical Center where he is the Pinkus Professor and director of the Early Phase Therapeutics Program. He was previously deputy director and chief scientific officer at Miami Cancer Institute, as well as the Dorothy M. Davies Chair in Cancer Research, tenured professor, and the director of the Division of Medical Oncology at the Ohio State University Comprehensive Cancer Center.

Villalona Calero's work is focused on the areas of lung cancer and developmental therapeutics, designing novel and more effective anticancer agents.

Over the past few years, he has been interested in genomic-driven therapy, in ways of targeting deficiencies in DNA repair with agents that target alternative mechanisms of repair, and in novel ways to use the immune system to target cancer. He has led/or is leading NIH-funded clinical trials and extensive correlative and preclinical work in these areas.

Steinhart, Foisey, Ganguly, Yamada-Hunter receive PICI Early Career Researcher awards

The Parker Institute for Cancer Immunotherapy, a collaborative consortium of the world's leading immuno-oncology experts, named its 2024 class of Early Career Researcher awardees.

This year's awardees will receive over $1 million in total to support their pioneering immunotherapy research, exploring approaches involving gene networks, synthetic receptors, metastatic stem cells, and engineered immune cells that could lead to life-saving treatments and bring us closer to a cure for cancer.

Now in its eighth year, the Early Career Researcher program has distributed 53 awards through 48 emerging investigators, with PICI deploying over $22.5 million since 2016 to advance high-impact immunotherapy research.

In addition to funding, awardees also gain access to PICI's world-class network of immunotherapy experts and research institutions, as well as leading-edge technology to further advance their research.

The 2024 Early Career Researcher awardees are:

- Zachary Steinhart, PhD, Gladstone Institutes, whose research focuses on the interrogation of gene networks controlling human cytotoxic T-cell function with next-generation CRISPR screens.

- Maxwell Foisey, PhD candidate, the University of California, San Francisco, whose research focuses on how novel hybrid synthetic receptors deliver immunomodulatory payloads, enhancing solid tumor T-cell therapy.

- Debolina Ganguly, PhD, Dana-Farber Cancer Institute, who is working to identify the mechanistic underpinnings by which metastatic stem cells promote systemic tolerance to tumor antigens and suppress responses to immunotherapy.

- Sean Yamada-Hunter, PhD, Stanford Medicine, who is studying harnessing engineered CD47 to develop T-cell and macrophage combination immunotherapy for rapid clinical translation.

Noam Auslander receives $600K grant to identify connections between gut microbial genes and melanoma immunotherapy

The Wistar Institute's Noam Auslander, assistant professor in the Molecular and Cellular Oncogenesis Program at the Ellen and Ronald Caplan Cancer Center, was awarded a $600,000 Women Scientists Innovation Award for Cancer Research grant from the V Foundation for Cancer Research.

The grant will support the next three years of Auslander's research. She plans to analyze microbial proteins from the guts of patients to determine how they may drive melanoma immune responses, with the ultimate goal of improving the clinical benefits of immunotherapy.

The V Foundation for Cancer Research was founded in 1993 by the late Jim Valvano, ESPN broadcaster and renowned basketball coach, and has allocated more than $353 million in grants for cancer research across the nation.

UAMS Winthrop P. Rockefeller Cancer Institute receives five NCI grants

Researchers at the Winthrop P. Rockefeller Cancer Institute at the University of Arkansas for Medical Sciences have been awarded five grants from NCI in 2024, totaling $4.6 million.

The new grants include:

- $3.3 million NCI grant to create a Melanoma Resistance Evolution Atlas. Principal investigator: Alan Tackett, Winthrop P. Rockefeller Cancer Institute deputy director,

- $421,000 NCI grant to study cancer-evolved resistance mechanism to enhance adoptive T-cells. Principal investigators: Tackett and Brian Koss, UAMS assistant professor of biochemistry and molecular biology,

- $393,000 NCI grant to study the mechanisms of TH17-DC immunotherapy for ovarian cancer. Principal investigator: Martin Cannon, UAMS professor of microbiology and immunology,

- $393,000 NCI grant to study SR-A as a therapeutic target in breast cancer. Principal investigators: Steven Post, UAMS professor of pathology, and Behjatolah Karbassi, UAMS associate professor of pathology,
- $153,000 NCI grant to study the development of immunocompetent melanoma brain metastases organoids. Principal Investigator: Analiz Rodriguez, UAMS associate professor of neurosurgery,
- The multimillion-dollar increase in highly competitive cancer research funding in less than three months comes on top of an existing $11.5 million COBRE grant awarded to UAMS in March by NIH to establish the Center for Molecular Interactions in Cancer.

Fred Hutch establishes scientific training program for high school and middle school teachers

Fred Hutch Cancer Center established Partners in Science 2.0 @ Fred Hutch, a summer research program that trains middle school and high school teachers in Fred Hutch labs to expand hands-on learning experiences they can take back to the classroom.

Over two summers, PS2@FH participants will focus on a collaborative biomedical research project with a Fred Hutch scientist.

Funded through the M. J. Murdock Charitable Trust, the program will be offered alongside the Hutch Fellowship for Excellence in STEM Teaching and Science Education Partnership teaching programs. These programs, along with student-focused summer programs, are all part of Fred Hutch's Science Education team's aim to increase diversity in the next generation of scientists.

Over 600 teachers have participated in science education programs at Fred Hutch since 1991, and this summer the Fred Hutch Science Education team expects over 160 students to take summer courses.

Summer programs for students and teachers include:

Science Education Partnership

Launched in 1991, this three-week program pairs scientists with teachers to get hands-on experience in laboratory research. These connections help scientists engage with communities and give teachers resources and new ideas to take back to the classroom.

Fred Hutch South Lake Union Campus, July 8 – 26 (Public Open House: July 26)

Hutch Fellowship for Excellence in STEM Teaching

This two-year research program for middle school and high school educators was established in 2017 and funded by NCI and private philanthropic donations. It centers on a cancer-focused research project along with the design of cancer-focused curriculum materials.

Fred Hutch South Lake Union Campus, July–August 2024 (Public Open House: Sept. 14)

Pathways Explorers

Rising 10th and 11th grade students spend two weeks touring working labs and meeting scientists at different stages of their careers.

Fred Hutch South Lake Union Campus, July 29 – Aug. 9, Aug. 12 – 23

Summer High School Internship Program

An eight-week, full-time, paid internship for rising 12th graders. They are immersed in mentored activities in a Fred Hutch research group. The program culminates with intern presentations to the Fred Hutch community.

Fred Hutch South Lake Union Campus, June 24 – Aug. 16

Coding for Cancer

A monthlong virtual program that connects students with computational biologists, teaches hands-on skills and shows how coding and computational tools are used in cancer research.

Fred Hutch South Lake Union Campus, July 29 – Aug. 23

The Science Education team recently received a $1.3 million, five-year NIH Science Education Partnership Award for a new program focused on cancer health equity. In addition to developing new curriculum and teacher offerings, it creates a new program specifically for Indigenous high school students led by Indigenous scientists and staff.

The two-week program will focus on engaging students in a culturally relevant science research project and learning about community health.

Beyond creating opportunities for students, teachers, and researchers to engage, the Science Education team develops free, open-source lessons with topics ranging from immunotherapy to mRNA vaccines.

The program's Intro to Cancer unit was recently designated as one of the few examples of a quality high school biology unit aligned to science standards used across the U.S., as part of the Next Generation Science Standards.

THE CLINICAL CANCER LETTER

CLINICAL ROUNDUP

FDA guidance provides new details on diversity action plans for clinical studies

FDA issued a draft guidance, "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies," to assist medical product sponsors in submitting diversity action plans to support certain clinical studies.

Diversity action plans are intended to increase clinical study enrollment of participants of historically underrepresented populations to help improve the data the agency receives about the patients who may potentially use the medical product.

Enhancing diversity within clinical studies not only facilitates broader applicability of results across a broad spectrum of patient populations, but also enhances understanding of the disease or medical product under study, thus providing valuable insights to inform the safe and effective use of the medical product among patients.

"Participants in clinical trials should be representative of the patients who will use the medical products," FDA Commissioner Robert M. Califf said in a statement. "The agency's draft guidance is an important step—and one of many ongoing efforts—to address the participation of underrepresented populations in clinical trials to help improve the data we have about patients who will use the medical products if approved."

This draft guidance describes the format and content of diversity action plans, the medical products and clinical studies for which a diversity action plan is required, as well as the timing and process for submitting diversity action plans to FDA.

The draft guidance also outlines the criteria and process the agency will use to evaluate a sponsor's request not to submit a required diversity action plan, also known as a waiver.

Diversity action plans must specify the sponsor's rationale and goals for clinical study enrollment (separated by the age group, ethnicity, sex, and race of clinically relevant study populations) and describe how the sponsor intends to meet those goals.

The guidance also urges sponsors and investigators to consider the many dimensions of clinical trial diversity, even those that extend beyond age, ethnicity, sex, and race, to enroll populations that represent the patients who will be treated if the product is approved.

The requirement for sponsors to submit diversity action plans comes from new provisions of the Federal Food, Drug, and Cosmetic Act added by the Food and Drug Omnibus Reform Act. These plans apply to phase III clinical studies or, as appropriate, other pivotal clinical studies of a drug or biological product, as well as for certain clinical studies of devices, including those intended to serve as the primary basis for the FDA's evaluation of the safety and effectiveness and benefit-risk determination of the device.

The requirement to submit a diversity action plan applies to clinical studies for which enrollment begins 180 days after publication of the final guidance.

"Generating data for a broader and more representative population early in the clinical development program is among the FDA's priorities to bring innovative medical products to the public," Richard Pazdur, director of the FDA's Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation and Research, said in a statement.

"With FDORA, there is now a requirement for sponsors to submit diversity action plans. These plans may help ensure that sponsors are thinking critically and intentionally about the many characteristics of the patient population they aim to treat when designing their clinical study," Pazdur said.

The draft guidance was developed by the Oncology Center of Excellence Proj-

ect Equity in collaboration with the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Office of Women's Health, and the Office of Minority Health and Health Equity.

Comments on the draft guidance should be submitted within 90 days after publication in the Federal Register to Regulations.gov. All written comments should be identified with the docket number and with the title of the guidance document.

Pan-cancer proteogenomics reveals potential drug targets

Researchers at Baylor College of Medicine and collaborating institutions have uncovered new potential therapeutic targets for cancer and new insights into existing cancer drug targets.

Using a comprehensive approach that included integrating proteomics, genomics, and epigenomics data from 10 cancer types, the team identified protein and small protein or peptide targets in cancer tissues and validated many of them experimentally as promising candidates for therapeutic strategies.

The study appeared in *Cell*.

"Experience has shown that targeted therapies, cancer treatments directed at specific proteins in cancer cells, hold promise for achieving more effective clinical results than traditional radiotherapy and chemotherapy," senior author Bing Zhang, professor of molecular and human genetics and part of the Lester and Sue Smith Breast Center at Baylor, said in a statement.

"Although there is progress identifying potential vulnerabilities of specific cancer types, fewer than 200 proteins are targeted by FDA-approved cancer drugs. In this study, we significantly expanded the list of potential therapeutic targets by analyzing data from more than 1,000 tissue samples spanning 10 cancer types."

The researchers applied computational tools to integrate proteogenomic data comprising genome-wide information on DNA, RNA, and proteins that was generated by the Clinical Proteomic Tumor Analysis Consortium from prospectively collected samples of treatment-naïve primary tumors, many with matched normal adjacent tissues for comparison.

The team integrated the CPTAC dataset with other public datasets to investigate the similarities and differences among gene and protein alterations found in diverse tumor types to illuminate protein targets for cancer therapy.

"Our goal was to better understand the characteristics of known drug targets. We also hoped to identify new targets that could lead to new drug developments," said Zhang, who is also a McNair scholar and member of Baylor's Dan L Duncan Comprehensive Cancer Center.

The team applied the data integration approach to systematically identify proteins and genes that are important for cancer growth and development.

For instance, proteins that are overexpressed or hyperactive in cancer tissues but not in normal counterparts, and loss of tumor suppressor genes, which can create dependencies on other proteins that could then be therapeutically targeted.

They also searched for tumor antigens, including neoantigens—cancer-specific peptides derived from gene mutations in tumors.

"Our study revealed new opportunities for repurposing drugs currently approved for other conditions," Zhang said. "For example, we show that an antifungal drug can also reduce growth of several cancer types, supporting further exploration of the anti-cancer value of this drug."

The researchers also identified potential protein targets currently without a drug—kinases and cell surface proteins. "These findings open opportunities for drug development, including small-molecule drugs or drug-antibody conjugates," Zhang said.

Furthermore, computational identification of several tumor-associated proteins shared among different cancer types was followed by experimental confirmation of their importance for cancer in cells grown in the lab and in animal models, validating these proteins as potential therapeutic targets worthy of more study.

Upregulating TERT gene expression reverses multiple hallmarks of aging

Researchers at MD Anderson Cancer Center have demonstrated that therapeutically restoring 'youthful' levels of a specific subunit of the telomerase enzyme can significantly reduce the signs and symptoms of aging in preclinical models.

If these findings are confirmed in clinical studies, there may be therapeutic implications for age-related diseases such as Alzheimer's, Parkinson's, heart disease, and cancer.

The study, published in *Cell*, identified a small molecule compound that restores physiological levels of telomerase reverse transcriptase, which normally is repressed with the onset of aging.

Maintenance of TERT levels in aged lab models reduced cellular senescence

and tissue inflammation, spurred new neuron formation with improved memory, and enhanced neuromuscular function, which increased strength and coordination.

The researchers show that TERT functions not only to extend telomeres, but also acts as a transcription factor to affect the expression of many genes directing neurogenesis, learning and memory, cellular senescence, and inflammation.

"Epigenetic repression of TERT plays a major role in the cellular decline seen at the onset of aging by regulating genes involved in learning, memory, muscle performance and inflammation," senior author Ronald DePinho, professor of cancer biology, said in a statement. "By pharmacologically restoring youthful TERT levels, we reprogrammed expression of those genes, resulting in improved cognition and muscle performance while eliminating hallmarks linked to many age-related diseases."

CHK1 inhibitor + rheumatoid arthritis drug could be therapy for NSCLC

The Ohio State University Comprehensive Cancer Center—Arthur G. James Cancer Hospital and Richard J. Solove Research Institute researchers have found a potentially effective drug-combination approach to treating certain patients with non-small cell lung cancer.

In a study published in *Nature Communications*, scientists show that a protein called checkpoint kinase 1 is critical for cell survival when the cells experience DNA replication stress. Drugs that inhibit CHK1 have been used with chemotherapy to kill cancer cells in preclinical studies, but this approach has been only minimally effective while causing substantial side effects in clinical trials involving humans.

To explore combination strategies that can overcome these limitations, the researchers studied an NSCLC cancer cell line, as well as tumors' response to CHK1 inhibitors, and discovered that blocking CHK1 can be more effective in killing NSCLC cells when combined with other proteins called thioredoxin1 and thioredoxin reductase, both of which are important components of the body's antioxidant system.

"This combination targets the cancer cells' ability to manage replication stress, making them more vulnerable to the treatment," senior author Junran Zhang, professor in the Department of Radiation Oncology at Ohio State and a member of the Cancer Biology Program at the OSUCCC—James, said in a statement.

Her team also found that a drug called auranofin, which is already used to treat rheumatoid arthritis, can enhance cancer cells' sensitivity to a CHK1 inhibitor drug that is currently being tested in a clinical trial for treating cancer patients.

"Our research results suggest a potential combinational approach to treating a subset of NSCLC patients and repurposing an existing drug (auranofin), originally used for treating rheumatoid arthritis, for use in oncology. Repurposing this drug in combination with CHK1 inhibitors for NSCLC treatment might be an area to focus on in future studies," said Zhang, who also is a member of the Pelotonia Institute for Immuno-Oncology and the Center for Cancer Metabolism.

The researchers note that, although auranofin has a well-known toxicity profile, the dose used to achieve its anti-cancer activity in current preclinical studies is higher than the dose used for treating rheumatoid arthritis, so the next clinical steps may be to validate the drug's effectiveness and safety in NSCLC or other tumor models involving an immune component host.

The team says more specific and potent drug inhibitors targeting Trx1 or TrxR1 need to be developed.

Tai Chi reduces risk of inflammatory disease, treats insomnia among breast cancer survivors

Both Tai Chi and cognitive behavioral therapy can reduce insomnia in breast cancer survivors but also may provide additional health benefits by reducing inflammation and bolstering anti-viral defenses, according to a study led by UCLA Health researchers. The work was published in *Brain, Behavior, and Immunity*.

Chronic insomnia is one of the most prominent symptoms experienced among cancer survivors and poses significant health concerns, including the risk of inflammatory disease that could increase the risk of cancer recurrence.

About 30% of breast cancer survivors are reported to have insomnia, which is twice the rate of the general population. While previous research has shown cognitive behavioral therapy and mind-body interventions such as Tai Chi are effective at treating insomnia among breast cancer survivors, less is known about their effectiveness in reversing inflammation caused by insomnia.

The study compared the two therapies among 90 breast cancer survivors using blood samples over 15 months to analyze changes in inflammation biomarkers.

Researchers found Tai Chi specifically led to more significant, sustained reduction in inflammation among par-

ticipants compared to cognitive behavioral therapy. By comparison, cognitive behavioral therapy participants had greater anti-viral gene transcripts, which potentially improve the body's defenses against infections.

"Tai Chi can be readily provided in community settings, with minimal cost, and can treat insomnia in adults, older adults and cancer survivors," first author Michael Irwin, professor at UCLA Health's Department of Psychiatry and Biobehavioral Sciences, said in a statement. "Further, Tai Chi, as compared to cognitive behavioral therapy, has additional advantage in reducing inflammation in breast cancer survivors."

The study relied on blood samples taken from breast cancer survivors from a 2017 study, also led by Irwin, that examined the effectiveness of Tai Chi versus cognitive behavioral therapy in insomnia treatment and remission. Blood samples were collected from 2008 to 2012 from the 90 participants from the Los Angeles area prior to treatment and at 2-, 3-, 6- and 15-month intervals. Researchers evenly split participants to either undergo weekly Tai Chi or cognitive behavioral therapy sessions lasting 120 minutes for a three-month period.

Analyses of the blood samples taken at the 15-month interval showed Tai Chi participants had reduced cellular and genomic markers of inflammation, specifically in plasma interleukin-6, TLR-4 stimulated monocyte production of inflammatory cytokines and inflammatory transcriptional profiles. Blood samples from the cognitive behavioral therapy showed greater increases in anti-viral gene transcripts.

"Effective treatment of insomnia has potent impacts on the immune system," said Irwin, who also directs UCLA Health's Mindful Awareness Research Center and is a member of the UCLA Health Jonsson Comprehensive Cancer Center.

"Tai Chi preferentially reduces inflammation as compared to cognitive behavioral therapy, whereas cognitive behavioral therapy preferentially improves antiviral viral immunity or resistance to infectious disease," Irwin said. "Further research that examines the combined benefit of Tai Chi and cognitive behavioral therapy is needed, especially in cancer survivors who are at risk for inflammatory disorder as well as infectious disease."

There were several limitations in the study and further studies are needed to test the effectiveness of these therapies across different populations. The participants were primarily white, older (ages ranging from 42-83), and had higher education.

The study also excluded participants who had coexisting medical conditions. Changes in participants' sleep-wake cycle and alignment with circadian rhythms may have also yielded these inflammatory health benefits.

Additionally, access to Tai Chi may be limited in some communities and requires ongoing practice for several days per week as compared to cognitive behavioral therapy.

Ongoing research is examining the trajectories of inflammatory activation and accelerated aging in breast cancer survivors, as compared to non-cancer control women, which will identify behavioral and biological targets for prevention of depression, as well other morbidities in cancer survivors.

Starpax announces magnetic field-controlled bacteria that deliver drugs to solid tumors

Starpax Biopharma Inc. announced its Starpax Cancer Treatment Platform, an innovation using living, self-propelled, non-pathogenic bacteria that carry anticancer drugs on their surface and are sensitive to magnetic fields.

With a 100% remission rate and no side effects in all the subjects of the company's preclinical trials, this technology is conceived to address all solid tumors, representing 90% of cancer and 89% of deaths.

The Starpax technology is addressing a major resistance problem to treatment that chemotherapy and immunotherapy haven't solved for over a century.

Studies have demonstrated that 90% of the volume of a tumor receives little or no drug at all. Drugs or immune cells need blood vessels to be distributed in a tumor and reach cancer cells, yet blood vessels and lymphatics in a tumor become chaotic, malfunctioning, or collapse.

More studies have also demonstrated that as little as 1% of the dose of systemic chemotherapy, such as nanocarriers, antibodies, and precision target drugs, reach a tumor, leaving 99% of the toxic doses free to circulate in the patient's body, attacking healthy organs and creating unwanted side effects.

The Starpax Magnetodrones are the first component of the Starpax Cancer Treatment Platform. The bacteria are injected directly into a tumor and can swim in tumors without using blood vessels or circulating in the bloodstream.

The Starpax PolarTrak is the second component of the platform. It is a proprietary medical device in which the patient is installed. It generates unique magnetic fields to keep the Magnetodrones captive inside the tumor, preventing them from escaping into the rest of the patient's body and forces the Magnetodrones to spread throughout

the whole volume of the tumor, including in hypoxic zones where the cancerous stem cells are located.

The process is managed by the Polartrak artificial intelligence, based on the data of the patient's tumor taken from the MRI imagery scanner days before the treatment.

Compared to modern systemic treatments, Starpax's technology allows the administration of up to 50 times more drug directly in the tumor, including hard-to-reach hypoxic zones.

By focusing treatment specifically on the tumor, Starpax's technology significantly lowers the risk of adverse effects. It allows 800 times fewer toxic molecules to be introduced into the body than standard chemotherapy treatments, drastically reducing toxicity and side effects.

The two-part platform of Magnetodrones and PolarTrak promises a safer, more effective alternative to traditional treatments.

To manufacture the Starpax Magnetrodrones, the company has also announced its new facility in Montreal is now in operation. When fully operational, the 27,000-square-foot facility has the capacity to produce Magnetodrones to treat 10,000 patients annually.

A second Magnetodrones manufacturing plant is being discussed, with a capacity of 110,000 patients annually.

Starting with two patents in 2017, Starpax now holds 57 key patents and pending patents for its Magnetodrones and PolarTrak. Since its founding, Starpax has collaborated with top cancer research institutions, including McGill University, Jewish General Hospital, Polytechnique Montréal, and TransMedTech Institute.

The company will begin clinical trials in 2025.

DRUGS & TARGETS

FDA approves Epkinly for R/R follicular lymphoma

FDA approved Epkinly (epcoritamab-bysp) for the treatment of adults with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

The drug is sponsored by Genmab A/S and Abbvie.

With this approval, Epkinly is the first and only T-cell engaging bispecific antibody administered subcutaneously approved in the U.S. to treat this patient population.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial(s).

FL is the second most common form of non-Hodgkin's lymphoma, accounting for 20% to 30% of all NHL cases. About 15,000 people develop FL each year in the U.S.

FL is considered incurable with current standard of care therapies, and patients often relapse. With each subsequent line of therapy, patients receiving currently available treatments may experience shorter durability of response.

The approval is based on results from the phase I/II EPCORE NHL-1 clinical trial, which evaluated the safety and preliminary efficacy of Epkinly in 127 adult patients with R/R FL who previously received a median of three lines of therapy and with 70% having double refractory disease.

The results showed an overall response rate of 82% and a complete response rate of 60%, including 67% of patients achieving minimal residual disease negativity.

Additionally, more than half of patients who responded to treatment in the study remained responsive to treatment at the time of data analysis (i.e., at a median follow-up of 14.8 months, median duration of response was not reached).

The study included prespecified subgroups representing patients with challenging-to-treat FL, including patients who were refractory to both anti-CD20 therapy and an alkylating agent, patients who were refractory to last prior treatment, and patients whose disease progressed within two years of first-line immunochemotherapy (POD24).

These results were recently published in the *Lancet Haematology*.

Common treatment-emergent adverse events (≥20%) from the FL cohort of the trial were injection site reaction, cytokine release syndrome, COVID-19, fatigue, upper respiratory tract infection, musculoskeletal pain, rash, diarrhea, fever, cough, and headache.

For patients who received Epkinly at the recommended 3 step-up dosage schedule, CRS was primarily low grade (40% Grade 1, 9% Grade 2). There were no grade 3 CRS events observed.

The prescribing information has a Boxed Warning for serious or life-threatening CRS and immune effector cell-associated neurotoxicity syndrome (ICANS).

Warnings and precautions include infections, cytopenias, and embryo-fetal toxicity.

EC approves Fruzaqla for previously-treated mCRC

The European Commission approved Fruzaqla (fruquintinib) as a monotherapy indicated for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with available standard therapies, including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapies, anti-VEGF agents, and anti-EGFR agents, and who have progressed on or are intolerant to treatment with either trifluridine-tipiracil or regorafenib.

The drug is sponsored by Takeda.

The decision follows a positive opinion from the Committee for Medicinal Products for Human Use on April 25, 2024, and approval by FDA for adults with mCRC who have been previously treated with oxaliplatin- and irinotecan-based regimens on Nov. 8, 2023.

The approval is based on results from the phase III multi-regional FRESCO-2 trial. The trial investigated Fruzaqla plus best supportive care versus placebo plus BSC in patients with previously treated mCRC.

FRESCO-2 met all its primary and key secondary efficacy endpoints and showed consistent benefit among patients treated with Fruzaqla, regardless of the prior types of therapies they received.

Fruzaqla demonstrated a manageable safety profile in FRESCO-2. Adverse reactions leading to treatment discontinuation occurred in 20% of patients treated with Fruzaqla plus BSC versus 21% of those treated with placebo plus BSC.

Data from FRESCO-2 were published in *The Lancet* in June 2023.

eHealth Technologies, CancerX collaborate to accelerate cancer innovation in U.S.

eHealth Technologies, a healthcare technology company, will join CancerX, a public-private partnership acting as a national accelerator, to boost innovation in the fight against cancer.

eHealth Technologies will join forces with the Digital Medicine Society and Moffitt Cancer Center in an effort to rapidly accelerate the pace of cancer innovation in the U.S., alongside the Office for the National Coordinator for Health Information Technology and Office of the Assistant Secretary for Health.

As a CancerX partner, eHealth Technologies will collaborate with other thought leaders in the oncology and digital health space to set priorities and practices that focus on achieving the goals of the Cancer Moonshot.

President Joe Biden reignited the Cancer Moonshot in 2022. The initiative aims to reduce the cancer death rate by 50% over the next 25 years and improve the experience of people and their families living with and surviving cancer.

The new partnership will leverage eHealth Technologies' extensive experience in helping healthcare organizations decrease time to treatment by ensuring clinical teams across the country have timely access to complete medical histories.

This allows clinicians to provide the right care plan and allows patients to have more meaningful initial appointments and get on the road to recovery as fast as possible.

Merck, Qure.ai collaborate to expand lung cancer detection via AI

Merck Global Health Innovation Fund has made a strategic investment into Qure.ai as part of its Series D round.

This funding will go towards investing into foundation models for artificial intelligence in imaging and expanding geographical reach of Qure.ai's AI-powered imaging solutions into the U.S. market.

Globally Qure.ai has delivered AI-augmented detection for tuberculosis, lung cancer, and stroke at over 2,700 imaging sites across more than 90 countries.

It has clearance from the FDA's Center for Devices and Radiological Health for its AI-powered chest X-ray lung nodule detection solution (qXR-LN); breakthrough device designation for TB solution (qSpot-TB); an AI-enabled head CT tool to expedite the detection, triage, and quantification of traumatic brain injuries and stroke (qER-Suite); plus multiple other plain film X-ray emergency room findings.

With ever-growing patient populations and burden of disease on health systems continuing to exert pressure, healthcare AI presents a huge opportunity to power early identification and management.

Merck had previously invested in Qure.ai, as part of its impact investing portfolio led by the Merck Office of Social Business Innovation.