FNIH
Foundation for the National Institutes of Health

2018 ANNUAL REPORT

ADVANCING BIOMEDICAL RESEARCH

BECAUSE

PATIENTS CAN'T WAIT.

ABOUT
THE FNIH

120+

ACTIVE RESEARCH, EDUCATION, TRAINING AND CAPITAL PROGRAMS

16

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The Foundation for the National Institutes of Health (FNIH) forges powerful alliances that advance breakthrough biomedical discoveries and improve the quality of people's lives. As a 501(c)(3) charity chartered by Congress, the FNIH creates and manages these partnerships with public and private institutions in support of the mission of the National Institutes of Health (NIH), the world's premier medical research agency. Convening otherwise diverse or competitive research efforts around a common mission, the FNIH brings dynamism, energy and urgency to finding treatments and cures for patients.

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DEAR FRIENDS,

AFTER DEVOTING TREMENDOUS ENERGY, KNOW-HOW AND RESOURCES TO TACKLE A PRESSING HEALTH CHALLENGE, A SCIENTIFIC DISCOVERY MUST MAKE PATIENTS BETTER.

This is why bringing the patient perspective into the research process early is critical. Patients are true research partners who contribute intellectually, but many times give of themselves by donating blood, tissue and their time. Without the patient perspective, it would be difficult to advance biomedical research that develops the tools required to fight disease and disability.

Through its programs, the FNIH harnesses vital patient perspectives alongside that of philanthropic, not-for-profit, foundation, government, academic and industry partners. Leveraging their collective expertise and resources around a shared scientific goal enables these diverse collaborators to achieve something far greater than any single entity can achieve alone.

This Annual Report highlights the FNIH's work throughout 2018 to build powerful alliances that accelerate and transform scientific understanding and research. The examples span from a project that is improving personalized cancer therapies to another that is evaluating a technology with the potential to eliminate malaria. By featuring the voices of patients and their advocates, the stories bring these critical viewpoints to the forefront.

As Big Data continues to enhance precision medicine, the future looks bright for patients. Earlier interventions, customized treatment plans and more efficient therapies are on the horizon. The FNIH looks forward to working with the public and private sectors to make this vision a reality — *because patients can't wait*. They need progress now.

Steven M. Paul, M.D.
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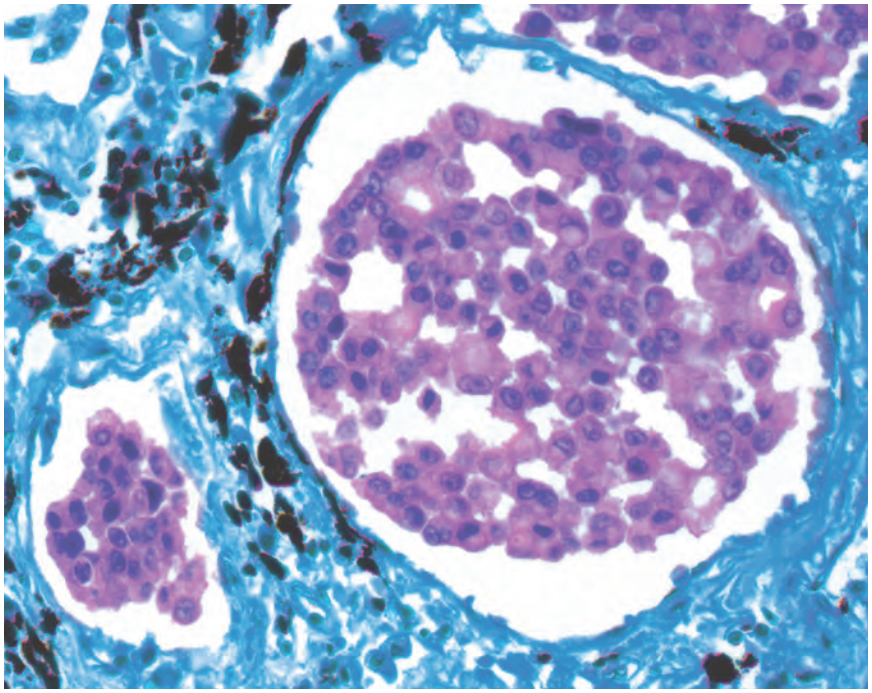
TRANSFORMATION

INVESTIGATING NEW TREATMENTS FOR LUNG CANCER PATIENTS

Carol "Annie" Burke



Non-small cell lung cancer cells exposed to an anti-tumor drug. (color adjusted)
Credit: National Cancer Institute \ Massey Cancer Center at Virginia Commonwealth University

"You hear the words come out of their mouths, that you have this horrible tumor in the middle of your chest, and you think: cancer means death. I was supposed to be gone 11 months after my initial lung cancer diagnosis. I have beat that by two years so far and I'm not stopping. I qualified for a new clinical trial, Lung-MAP, that was going to be a lifesaver, and it worked for me. I know how blessed I am."

— Carol "Annie" Burke, Lung-MAP patient

Shortness of breath. Exhaustion. Loss of appetite. These are just some of the symptoms experienced by patients with lung and bronchial cancer, which remains the second most common cancer diagnosis in the United States according to the National Cancer Institute (NCI). About 85 percent of those diagnosed have non-small cell lung cancer, a disease in which cancer cells form in the tissues of the lung.

In 2018, the FNIH, NCI and partners prepared for a major expansion of the Lung Cancer Master Protocol (Lung-MAP) clinical trial. The trial previously tested treatments for people with advanced stage squamous cell lung cancer. It is now open to patients with all types of advanced stage non-small cell lung cancer. This development will enable thousands of new patients to enroll in Lung-MAP, joining the more than 1,800 patients, like Annie Burke, already participating at 640 U.S. medical centers and community hospitals across the country.

Launched in 2014, Lung-MAP is the first major NCI cancer trial to test multiple cancer treatments simultaneously under one "umbrella" design. This pioneering research model is more flexible and faster than traditional clinical trials as it enables researchers to share one trial structure and recruitment process. Patients are tested once for more than 200 cancer-related genetic alterations before they are assigned to investigational treatment studies based on their unique tumor profile. Patients without a matching genetic alteration for a corresponding therapy within Lung-MAP are placed on an immunotherapy regime.

"A great thing about the Lung-MAP design is that the patients can move from one study to the next to the next," said Jessica Jordan, Research Coordinator, VA Connecticut Healthcare Systems. "Every single study these days requires tissue. We only have to submit one block of tissue and a patient is potentially able to receive more than one line of treatment on the trial if their general health allows. That's the major benefit."

The trial has already completed seven out of 10 launched studies, with two more sub-studies scheduled to open in 2019, offering patients a personalized approach to finding the investigational drugs that will fight their cancer.

Read more at fnih.org/LungMAP.

IMPROVE DIAGNOSIS OF KIDNEY INJURY

"Kidney function is important for day-to-day living. You can afford to lose one kidney, as can be seen with live kidney donors, but once you lose 75 percent of function then you start to suffer from kidney failure. Complications can be quite serious and untreated kidney failure would lead to death. So, kidney safety is an important issue that comes up in drug development."

— Stefan Sultana, M.D., Renal Safety Expert within the Patient Safety Group of AstraZeneca and Kidney Safety Project Team Member

In 2018, the FNIH Biomarkers Consortium achieved an unprecedented milestone by receiving the first ever qualification of a clinical safety biological marker (biomarker) awarded by the U.S. Food and Drug Administration (FDA). The qualification applies to a composite measure of six urine biomarkers that reliably change in response to drug-induced kidney injury prior to irreversible damage and earlier than traditional biomarkers. This set of biomarkers can now be used to aid in the detection of acute kidney injury in healthy volunteers during early phase clinical trials. It will help improve the development of safe and effective medicines for patients where concern has been raised that an investigational drug may cause kidney injury.

This major milestone was made possible by the relentless efforts of government, not-for-profit and industry partners sharing intellectual and financial resources to fast-track the development of these critical biomarkers. The pathway set forth by the team may help others submitting biomarkers for qualification by the FDA, explained Stefan Sultana, M.D.,: "The cutting-edge is a lonely place to be because no one has been down this path before, so we're developing new science and new ways of doing things with the regulatory agencies. Hopefully the lessons we learned make it a lot easier for other groups to pursue qualification of safety biomarkers."

Read more at fnih.org/KidneySafety.

TRACKING KNEE OSTEOARTHRITIS

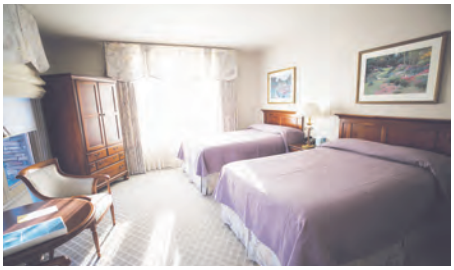
"Osteoarthritis is a condition that I never thought I'd be dealing with because I'm a fitness instructor and healthy. About 12 years ago, I started getting these pains, heard creaking in my knees and then the doctor told me that I had bone-on-bone in my knees. I was shocked. We need research to help us see changes earlier so that we can stop the progression."

— Cindy Copenhaver, Arthritis Foundation Ambassador

Millions of people worldwide will experience osteoarthritis as they age, as it is the most common disorder of the joints and a major cause of disability in older adults. Despite its prevalence, there remains a lack of tools to accurately evaluate patients, which makes it difficult to develop new treatments.

In 2018, the FNIH Biomarkers Consortium launched a new project that will help physicians and patients, like Cindy Copenhaver, better understand knee osteoarthritis. Researchers will seek regulatory qualification of a new set of imaging (i.e., MRI) and biochemical (i.e., urine, serum) biomarkers that predict structural changes in the joint caused by knee osteoarthritis over time. The FNIH identified these biomarkers through a previous project and showed that they more precisely predict and monitor changes in the knee compared to the current standard that uses x-ray images. The acceptance of these biomarkers for the development of new drugs will pave the way for improved treatment options for osteoarthritis patients.

Read more at fnih.org/ProgressOA.



A few of the renovated rooms at the Edmond J. Safra Family Lodge.

RENOVATING A SAFE HAVEN FOR NIH PATIENTS AND FAMILIES

David Haas

"My wife, Nachama, and I enjoy staying at the Edmond J. Safra Family Lodge when I am treated at the NIH Clinical Center. Especially after a long day of tests and appointments, it is great to come back to a place that is familiar and welcoming, instead of having to leave campus and travel to a hotel."

— David Haas

Participating in medical research is often the last chance for patients to find a new, potentially life-saving therapy to fight their disease. Patients and their families travel far from home to access clinical trials, leaving work behind to live in hotels for months — a reality that can be draining, stressful and costly.

During this difficult time, the Edmond J. Safra Family Lodge provides a haven for these brave families on the NIH campus. Adult patients participating in medical research at the NIH Clinical Center and their families can stay at the Family Lodge at no cost to them. In 2018, the FNIH and NIH, with support from FNIH Board Member Lily Safra and the Edmond J. Safra Foundation, partnered to renovate the Family Lodge, which was showing signs of wear after 12 years of continuous use. The team delicately balanced minimizing disruption to the daily operations while making enhancements, such as new lighting, paint, carpet and drapery, for the 34 guest rooms and common areas.

"They did a great job with renovating the Family Lodge," said David Haas. "It has been an important part of my family's journey at the NIH. From talking with other guests, I hear different stories about how NIH's cutting-edge research is helping people from all over the world. It's vitally important that they continue that work, and that families have a place to stay nearby."

Read more at fnih.org/FamilyLodge.

ACCELERATION

A NEW TOOL WITH POTENTIAL TO ELIMINATE MALARIA

Fredros Okumu, Ph.D.

The Plasmodium parasite causes malaria by infecting red blood cells.

"When kids are affected by malaria they are absent from school, and their parents lose days of work and the daily wages the family depends on. There is also psychological distress of losing family members from a disease that is largely treatable. That impact is much bigger than what we can compute in terms of just number of cases and deaths."

— Fredros Okumu, Ph.D.,
Ifakara Health Institute, Ifakara,
United Republic of Tanzania

Following years of success in reducing malaria across the globe, progress has stalled. According to the World Health Organization, there were an estimated 219 million cases of malaria in 2017, an increase from 217 million in 2016. Reductions in mortality rates have similarly plateaued and scientists, countries and communities find themselves at a critical juncture.

"There has been little innovation in malaria control and so for the first time with the coming of technology like gene drive, particularly after the discovery of the gene editing technique CRISPR, many of us started to believe that we have a tool now that could potentially be revolutionary. Nonetheless, more research is needed to assess benefits and risks. And that's what we are asking our scientists to do," explained Fredros Okumu, Ph.D.

Gene drive is a mechanism that promotes the preferential inheritance of a genetic trait to increase its prevalence in a population. Recent advances in gene editing allow this natural mechanism to be mimicked in the laboratory. Many applications of this emerging technology are being considered, including its use on mosquitoes to reduce the transmission of mosquito-borne diseases, such as malaria. As the technology is still in its early stages, it requires careful consideration and assessment before gene drive products can be field-tested and deployed.

The FNIH is working with partners like Dr. Okumu to facilitate important discussions on gene drive technology among various stakeholders to develop and share best practices, technical advice and training to advance responsible research. In 2018, Dr. Okumo was part of an FNIH-led working group that presented their paper at the American Society of Tropical Medicine and Hygiene (ASTMH) Annual Meeting, which outlines recommendations for the safe and ethical testing of gene drive technology on mosquitoes to reduce the burden of malaria transmission in Africa. Previously published in ASTMH's scientific journal, the paper proposes a pathway for the responsible development and testing of gene drive products.

"Our interest now is to encourage scientists to investigate the potential of the technology," said Dr. Okumu. "If we don't do scientific research on this technology then we won't be able to understand it. Given the complexity associated with this tool, it is only right to bring everyone together to try to make sure people are speaking the same language. Maybe for the first time, if we do things right, we could have a tool that dramatically shifts the needle towards the dream of malaria elimination which has been elusive for a long time."

Read more at fnih.org/genedrive.

SHAPING PERSONALIZED CANCER THERAPIES

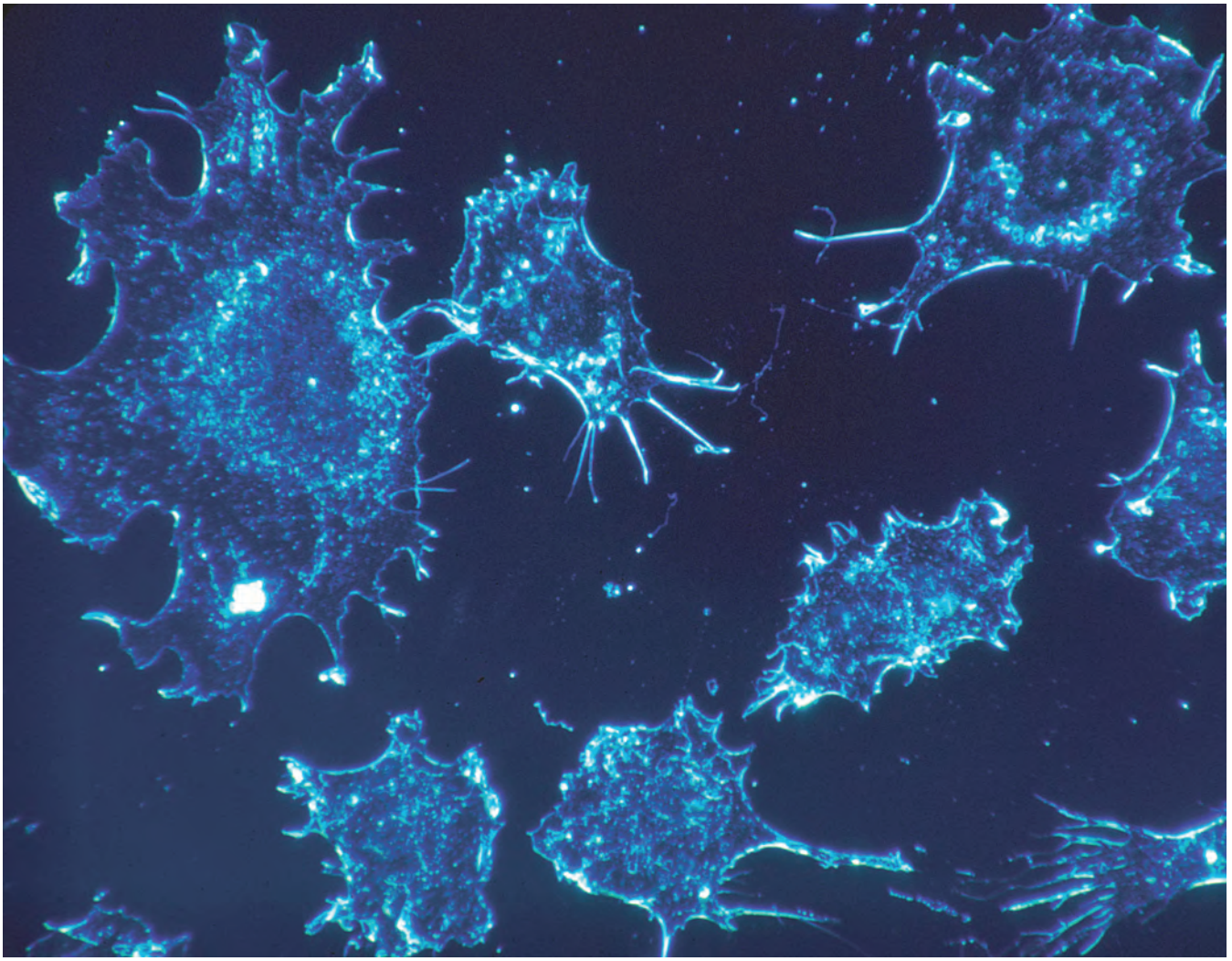
Jeffrey S. Abrams, M.D.

Nearly everyone has a family member or friend affected by cancer. Fortunately, recent advances in immunotherapies have shown promising responses in certain cancer types. What researchers still need to uncover is how and when to best pair an immunotherapy to a specific patient.

In 2018, the FNIH, NIH, FDA and 12 pharmaceutical companies continued their work to better understand how immunotherapies are effective in some patients and to accelerate the development of new treatments through the Partnership for Accelerating Cancer Therapies (PACT). Leveraging their collective expertise, capabilities and resources, the partners set out to identify and develop robust, standardized biomarkers and tests that will support the selection and clinical testing of immune-oncology and combination therapies for patients. These biomarkers and tests will be shared with the broader research community so that they can be used effectively in clinical trials conducted anywhere in the cancer field.

"The PACT team has worked across barriers to bring different people together to do something that would be difficult to do alone," explained Jeffrey Abrams, M.D., Director, Clinical Research, Division of Cancer Treatment and Diagnosis, and Associate Director of the Cancer Therapy Evaluation Program, National Cancer Institute (NCI), retired. "The challenge of our time will be to make immunotherapies work even better for individual patients to generate the rapid progress that we'd all like to see."

Read more at fnih.org/PACT.



Cancer cells in culture from human connective tissue.
Credit: National Cancer Institute

Melinda Bachini

"For every patient that is diagnosed, all they need to hear about is the patient who did well. When I tell people that I'm a nine-year, stage 4 survivor of Cholangiocarcinoma it gives them hope to know that research is being done and progress is being made. With all of the new targeted therapies and immunotherapies being done, I feel like we have more hope for all diseases than we've ever had before."

— Melinda Bachini

EXPANDING THE ACCELERATING MEDICINES PARTNERSHIP

The Accelerating Medicines Partnership (AMP) has served as an effective vehicle for public-private partnerships in biomedical research since 2014. AMP initially brought together the FNIH, NIH and FDA with not-for-profit organizations and industry to accelerate early-stage drug development in Alzheimer's disease, type 2 diabetes and the autoimmune disorders rheumatoid arthritis (RA) and systemic lupus erythematosus. By enabling joint planning of research in the highest areas of need and sharing resources, expertise and data, AMP has made significant progress in understanding disease pathways at the molecular level and in identifying new targets for treatments. All of the data generated from AMP are made broadly available to the research community through online knowledge portals for use in drug discovery and development.

In 2018, the AMP team expanded work in two key areas:

- **Launch of AMP Parkinson's Disease (AMP PD):**

  The number of people living with Parkinson's disease is expected to nearly double by 2040, according to the National Institute of Neurological Disorders and Stroke, and there are still no disease-modifying drugs (NINDS) approved for treatment. Through the new AMP PD program, researchers will transform the current model for developing diagnostics and treatments for patients by identifying and validating biomarkers that track disease progression and serve as new drug targets.

- **Extension of AMP RA/ Lupus to a 6th Year:**

  This program extension will enable researchers to deploy emerging technologies that can further analyze tissue, blood and urine samples from patients living with RA or Lupus. The program will create a more detailed understanding of the molecular nature of these diseases. By examining samples at the single-cell level researchers are identifying the genes, proteins and chemical pathways that play important roles in these diseases and uncovering new targets for drug development.

Read more at fnih.org/AMP.

THE CRITICAL ROLE OF CLINICIAN-SCIENTISTS

"I believe that bridging the gap between clinical care and research is critical to finding new treatments."

— Michael Fox, M.D., Ph.D., winner of the FNIH 2018 Trailblazer Prize for Clinician-Scientists

Clinician-scientists fulfill an essential and unique role in medicine. They conduct research that applies basic scientific knowledge to clinical problems — ultimately harnessing discovery from the laboratory and applying it directly to patient care. Yet, the number of those embarking on careers in this vitally important field is declining.

In 2018, the FNIH launched the Trailblazer Prize for Clinician-Scientists, made possible with generous support from John I. Gallin, M.D., and Elaine K. Gallin, Ph.D., to recognize the outstanding contributions of early career clinician-scientists whose work has the potential to or has led to innovations in patient care. The Trailblazer Prize is an opportunity to shine a light on the essential medical contributions of clinician-scientists and inspire the next-generation to join the field.

After receiving more than 100 nominations, the jury selected three finalists: Daniel Bauer, M.D., Ph.D., Harvard Medical School, Jaehyuk Choi, M.D., Ph.D., Feinberg School of Medicine, Northwestern University and Michael Fox, M.D., Ph.D., Beth Israel Deaconess Medical Center, Harvard Medical School. In October, the finalists joined the FNIH for an event on Capitol Hill to explain their research and offer insights about their profession to congressional staffers. The FNIH Annual Fall Board Dinner followed that evening, where the FNIH announced Dr. Fox as the prize winner for pioneering innovative techniques to map human brain connectivity that can be translated into new treatments for neurological diseases.

"The purpose of our lab is to translate human brain connections into new patient care," explained Dr. Fox. "As we learn that different symptoms map to different brain circuits, we tailor our treatments to those symptoms, rather than treating all patients the same way. One of my patients had Parkinson's disease and a medication refractory tremor. Through deep brain stimulation therapy, he experienced not having the tremor for the first time in 12 years."

Dr. Fox's work exemplifies how clinician-scientists drive innovations for patient care. Through the Trailblazer Prize, the FNIH will continue to showcase their significant contributions that can be life-changing for patients now and in the future.

Read more at fnih.org/TrailblazerPrize.

Trailblazer Prize finalists Drs. Daniel Bauer and Jaehyuk Choi, alongside Trailblazer Prize winner Dr. Michael Fox, speak with FNIH Chairman Dr. Steven M. Paul at the FNIH Annual Fall Board Dinner.

WAYS TO GIVE

"I support the FNIH because a gift can help save people and entire families. The NIH helped my family understand what happened to so many of them, why these people died and what was going on. Now they know and can make choices and seek treatment. It's a miracle that they were able to do that in just one generation."

— Carrie Trahan

Carrie Trahan with her sons Aaron and Kyle.

Carrie Trahan's son Kyle was the first patient that NIH researchers found living with a rare kidney cancer called Hereditary Leiomyomatosis and Renal Cell Cancer (HLRCC). After testing other family members, it became clear that HLRCC was the disease experienced by Kyle's late father and many others. By studying the family's samples, scientists soon discovered the genetic marker for HLRCC. A few years later, they even developed a simple blood test to identify patients with the disease and are exploring treatment options. The Trahan family made these incredible scientific advances possible.

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FINANCIAL HIGHLIGHTS

REVENUE AND SUPPORT	2018	2017
Contributions	$58,261,723	$58,518,484
Grants	116,338	381,969
Administrative fee	64,723	111,660
Transfers from NIH*	2,000,000	1,110,000
Investment income	917,698	2,321,843
In-kind contributions	256,859	1,490,818
Donated services	60,000	39,000
Fundraising event	368,156	324,700
Total revenue and support	**$62,045,497**	**$64,298,474**

EXPENSES AND CHANGES IN NET ASSETS	2018	2017
Program services		
Fellowships and training programs	$1,074,653	$958,145
Memorials, awards and events	486,093	813,509
Capital projects	852,380	66,782
Research programs	34,264,962	49,897,652
Total program services	**$36,678,088**	**$51,736,088**
Supporting services		
Management and general	$5,436,683	$4,864,695
Fundraising	515,538	438,402
Total supporting services	**$5,952,221**	**$5,303,097**
Total expenses	**$42,630,309**	**$57,039,185**
Change in net assets	$19,415,188	$7,259,289
Net assets beginning of year	110,487,619	103,228,330
Net assets at end of year	**$129,902,807**	**$110,487,619**

**Reflects Transfers from NIH for 2018 and 2019 Federal Government Fiscal Years.*

2018 EXPENSES

80.3%
Research Partnerships

14%
Management and Fundraising

5.7%
Education and Events

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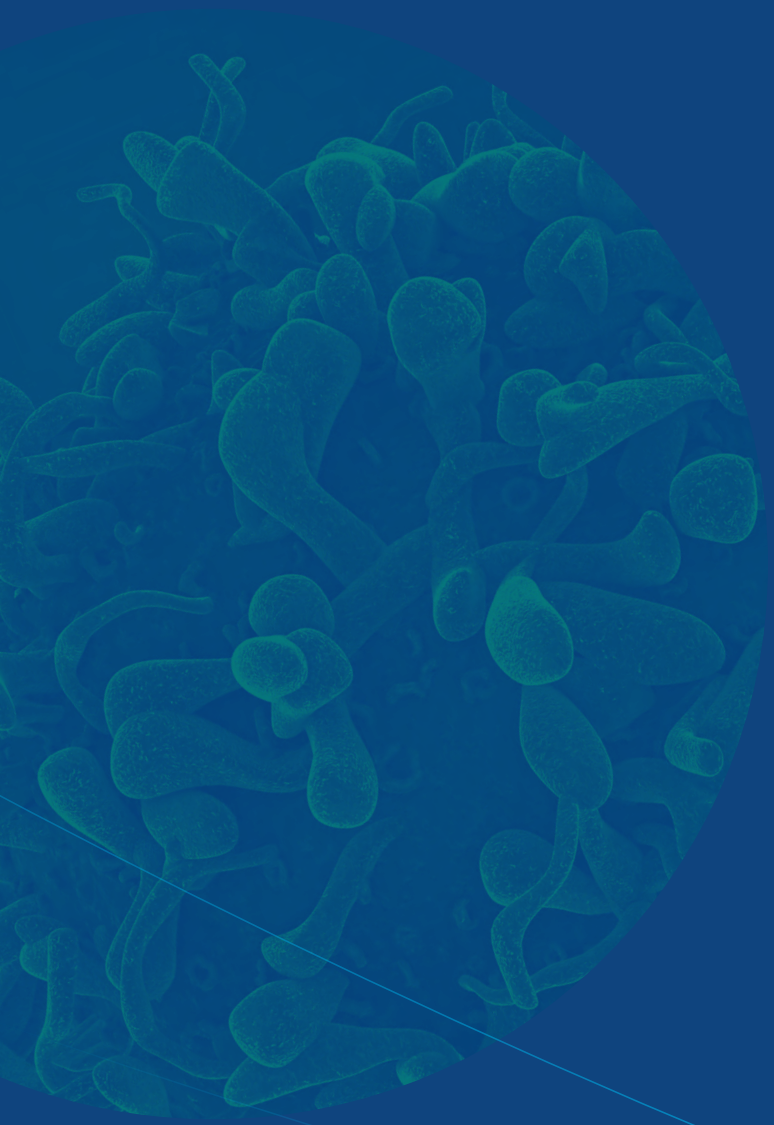

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