RESEARCH BRINGS US ONE STEP CLOSER TO

UNDERSTANDING  BREAKTHROUGHS  SOLUTIONS

2019 ANNUAL REPORT
## Impact Highlights

**As we embark on a new decade, the Foundation for the National Institutes of Health (FNIH) is proud to continue supporting the field of biomedical research. Presented here are a few significant milestones from the past decade resulting in meaningful impact in health worldwide.**

<table>
<thead>
<tr>
<th>Created</th>
<th>Developed</th>
<th>Revealed</th>
<th>Pioneered</th>
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<td>Created the infrastructure for unparalleled public-private partnerships to accelerate development of new treatments for chronic diseases like Alzheimer’s disease, type 2 diabetes, rheumatoid arthritis, lupus and Parkinson’s disease, by sharing data publicly to advance the science and establish a model for progress.</td>
<td>Developed the first-ever evidence-based criteria to diagnose sarcopenia, which will promote the generation of better therapies to treat this condition.</td>
<td>Revealed that exposures to pathogens in children in low-resource settings leads to significant shortfalls in child development — even in the absence of symptoms of any disease — through a paradigm-shifting study.</td>
<td>Pioneered the use of a master protocol for clinical trials in oncology, leading to rapid acceleration of cancer drug testing, extending treatment access to hundreds of cancer patients and paving the way for master protocol use in other disease areas.</td>
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**Read about it:** [fnih.org/AMP](fnih.org/AMP)  
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DEAR FRIENDS,

IT HAS BEEN SAID THAT SCIENCE IS A VERB: A DYNAMIC PROCESS OF DISCOVERY, INNOVATION AND TRANSLATION.

Put in action, science can solve some of the greatest health challenges facing the world today. Research brings us one step closer to doing just that. The exploration taking place now in research laboratories supported by the National Institutes of Health (NIH) and at the NIH has enabled a more profound scientific understanding of disease than ever before. These new insights lead to novel methods and techniques that facilitate breakthroughs in the ways we diagnose, treat and prevent disease. Such groundbreaking approaches, in turn, make possible practical solutions for health challenges faced by people across the globe.

In these pages, you will see examples of biomedical research moving the needle forward. In 2019, the FNIH launched initiatives that anticipate patients’ response to cancer treatment, ease the burden of diagnosis of a common, deadly liver disease and improve the tuberculosis vaccine — to name just a few. These stories illustrate the unique and crucial role of the FNIH: building and managing cross-sector alliances, convening key stakeholders to tackle complex challenges, investing in the future of scientific leadership, and sharing the results of our collaborations to advance knowledge among the research community.

There is no better example of the importance of our work than our support of the NIH in its urgent and heroic efforts to combat COVID-19 through clinical trials for vaccines and treatments. It has never been clearer that public-private partnerships are critical to solving humanity’s most pressing public health challenges. Collaborations with partners from industry, government, not-for-profit organizations, foundations and individual donors leverage generosity, dedication and expertise to move toward the types of health care solutions that will make a huge difference in all of our lives.

Above all, we wish to highlight our gratitude for your partnership and support in carrying out the mission of the FNIH. Just as research brings us one step closer, research brings us together around the shared desire to achieve our grandest, most transformative goals for human health.

Steven M. Paul, M.D.
Chairman

Maria C. Freire, Ph.D.
President and Executive Director
EXPLORATION AND DISCOVERY BRING US ONE STEP CLOSER TO SCIENTIFIC UNDERSTANDING.
Each year in the United States, an estimated 50,000 people will receive the devastating news of a diagnosis with Parkinson’s disease. Second only to Alzheimer’s disease as the most common age-related neurodegenerative disorder, Parkinson’s disease affects approximately half a million Americans, a number that is expected to triple over the next 50 years as the population ages.

Parkinson’s disease and its hallmark symptoms of tremors and stiffness are unfortunately very well-known to many people. Yet there is much left to learn about the disorder as researchers work to understand the underlying causes, to better predict the disease and its progression, and to develop more effective treatments for patients.

Enter AMP PD, the Accelerating Medicines Partnership for Parkinson’s Disease. A public-private partnership between NIH, biomedical and pharmaceutical companies and a not-for-profit organization, managed by the FNIH, AMP PD is one of the AMP collaborations uniting sectors to transform research in high-priority disease areas such as Alzheimer’s disease, type 2 diabetes, and rheumatoid arthritis and lupus. AMP PD will revolutionize the field of Parkinson’s disease research through its alliance of experts working to identify and validate promising treatment targets for the disease, with the ultimate goal of improving outcomes for patients.

In 2019, AMP PD launched a groundbreaking data portal to grant researchers working on Parkinson’s disease unprecedented access to the de-identified health information of more than 4,000 people. Such access allows scientists to study and analyze complex data sets at a scale previously unthinkable.

The first step was harmonizing the data, a crucial process that ensures the information is entered in an accurate, consistent way and that enables the comparison of data from many different sources. Looking forward, this establishes the standard for harmonized databases.

“AMP PD is a true example of the whole being greater than the sum of its parts. The combination of many data sets could allow researchers greater power to analyze potential biomarkers for Parkinson’s disease,” says Walter Koroshetz, M.D., director of the National Institute of Neurological Disorders and Stroke. “This effort follows other AMP programs which have the shared goal of changing the way we go about the business of studying disease.”

Read more at fnih.org/amp-pd.
BETTER PREDICTING A PATIENT’S RESPONSE TO CANCER TREATMENT

Every tumor adapts to its unique place of growth within the body. These changes create complex ecosystems, each made up of different kinds of cells. The interactions within these microenvironments can be analyzed to determine how cancer progresses and how it is affected by anti-cancer treatments. A deeper understanding of these processes will shed light on how two common forms of cancer treatment — immunotherapy and chemotherapy — might best be used in concert to improve health outcomes for cancer patients. The need for that better understanding is why the FNIH launched a project called Chemotherapeutic Impact on the Immune Microenvironment, or ChIIME.

The fastest-growing type of cancer treatment is immunotherapy, which stimulates the body’s natural immune system to attack cancer cells. It has shown great success for some kinds of cancers and some patients, but not all. Scientific evidence suggests that introducing chemotherapy before immunotherapy — or doing both at the same time — can alter the microenvironment, improving the odds of successful treatment.

Led by experts from the FNIH, the National Cancer Institute (NCI), the FDA, academia and industry, the ChIIME project uses a cutting-edge technology called single nucleus RNA sequencing to analyze the microenvironment of breast cancers that are particularly resistant to most therapies. The analysis technique allows for a clearer picture of all cell populations in the microenvironment, interactions among different cells and features that explain tumor cells’ responses to treatment. Studying breast cancer samples in this way, scientists will learn more about the effects of chemotherapy on different kinds of cells, including immune cells.

Ultimately, the insights gleaned from this investigation will be used to develop biomarkers that inform therapeutic decisionmaking. The knowledge will help to guide the ways that therapies are designed and assigned to patients, potentially leading to new and better treatment options for people with cancer.

Read more at fnih.org/chiime.
STANDARDIZING THE ASSESSMENT OF GENETIC TESTS USED TO TRACK CANCER

As a cancerous tumor progresses and grows in a person’s body, it often sheds cells. These cells are broken down in the body, releasing material into the bloodstream, including DNA known as circulating tumor DNA, or ctDNA. This ctDNA can be studied by scientists to determine genetic mutations in the tumor that can be targeted for treatment. These mutations can also help explain a tumor’s resistance to treatment.

Because of the many uses of ctDNA and the simple way in which it is obtained — through a blood sample — a host of technological advances have been developed to analyze it. This has been highly beneficial in providing crucial diagnostic information to doctors, patients and cancer researchers, but the proliferation of technologies gives rise to a lack of standardization. Hospitals and laboratories across the country are capturing and analyzing ctDNA but lack a uniform set of universally recognized standards to guide interpretation of the results. The same sample can be interpreted very differently by different scientists, making it difficult to fully understand or trust any given test.

In 2019, the FNIH launched a project called Identification and Validation of ctDNA Quality Control Materials. A partnership spanning the public, private and academic sectors, the ctDNA project will develop much-needed universal standards. The project will create a set of quality-control materials meant to provide assurance that all testing steps were correctly performed, allowing for comparison of samples across different hospitals and laboratories and better enabling accurate results.

Once successfully developed and disseminated, these quality-control materials will help lay the groundwork for more effective clinical research, as well as faster regulatory approval of new testing technologies and how they might be used to help patients. The project is likely to lay a foundation for the development of protocols to test other genetic material in the future, with implications that could reach far beyond even those for people with cancer.

Read more at fnih.org/ctDNA.
NOVEL APPROACHES BRING US ONE STEP CLOSER TO **BREAKTHROUGHS** IN CONDUCTING BIOMEDICAL RESEARCH.
IMPROVING THE PATIENT EXPERIENCE IN DIAGNOSING A DEADLY LIVER DISEASE

According to the American Liver Foundation, roughly 5 percent of U.S. adults — or 16.5 million people — are affected by a type of liver disease called NASH: non-alcoholic steatohepatitis. Characterized by buildup of fatty tissue in the liver, NASH continues to increase in prevalence alongside rising rates of obesity and type 2 diabetes. Unfortunately, NASH does not present symptoms until a patient is in the later stages of the disease; when left untreated, the disease can cause permanent damage. Currently, the disease can only be diagnosed through a painful, invasive and expensive liver biopsy. To properly diagnose NASH, and to help doctors identify patients at risk of dire health complications like liver failure or cancer.

“The there is a broad consensus on the need to validate safe and simple approaches to replace biopsy for diagnosis and staging, and as a way to monitor the liver health of patients with NASH over time,” says Gail Cawkwell, of partner Intercept Pharmaceuticals. “We will get there faster if academic institutions, patient groups, drug developers, regulators and public health agencies all work together to pool our data, resources and knowledge.” Morris J. Birnbaum, of partner Pfizer, says, “NIMBLE has the potential to galvanize the entire field in our pursuit of an accurate, scalable, non-invasive tool for the diagnosis and staging of NASH.”

A breakthrough discovery in the diagnosis and monitoring of NASH is an essential goal for the research community, potentially helping patients with this deadly, yet invisible, disease.

Read more at fnih.org/NIMBLE.
INVESTING IN THE FUTURE OF SCIENTIFIC LEADERSHIP

One of the many ways the FNIH accelerates progress is through investment in the creativity of exceptional scientists. The organization bestows three prizes each year to recognize outstanding partners and contributors to advancing biomedical research.

LURIE PRIZE IN BIOMEDICAL SCIENCES
The Lurie Prize in Biomedical Sciences is an annual prize made possible by a gift from philanthropist Ms. Ann Lurie, recognizing outstanding achievements made by a promising young scientist. In May, the FNIH honored Yasmine Belkaid, Ph.D., of the National Institute of Allergy and Infectious Diseases (NIAID) for revolutionizing our understanding of microbes in the gut and skin.

Dr. Belkaid’s groundbreaking work has shed light on the interaction between the microbiome and the immune system, as well as the crucial implications of this interaction for human health. Her research is focused on using microbes to develop novel strategies to prevent and treat diseases such as psoriasis, Crohn’s disease, allergies and autoimmune diseases. By transforming the understanding of the microbiome’s critical function in human health, Dr. Belkaid’s research paves the way for yet further breakthroughs in disease diagnostics and management.

Read more at fnih.org/LuriePrize.

TRAILBLAZER PRIZE FOR CLINICIAN-SCIENTISTS
The Trailblazer Prize was established in 2018 to highlight the essential role of early career clinician-scientists in spurring innovation in patient care.

In October, Dr. James Kochenderfer of NCI was announced as the prize winner for pioneering the development of immunotherapies that leverage chimeric antigen receptor (CAR) T-cells to treat blood cancers. His work led to the first approval by the FDA of a CAR T-cell therapy for lymphoma. He also headed the first clinical trials focused on a specific antigen for the treatment of multiple...
myeloma. Dr. Kochenderfer’s work is a premier example of how clinical science has the potential to create life-saving breakthroughs in the treatment of cancer.

Funding for the Trailblazer Prize is provided by the Gallin Fund at the FNIH.

Read more at fnih.org/TrailblazerPrize.

CHARLES A. SANDERS, M.D., PARTNERSHIP AWARD
Each year, the FNIH bestows the Charles A. Sanders, M.D., Partnership Award to recognize people and/or organizations that have made significant contributions to the organization’s efforts to build, implement and nurture public-private partnerships in support of the mission of the NIH. In 2019, the FNIH proudly honored the Doris Duke Charitable Foundation and Jane Sayer, Ph.D., for their steadfast support of NIH training and awards programs to foster the research community and for their ongoing work to further the Foundation’s mission.

Funding for the Charles A. Sanders, M.D., Partnership Award is provided by the Charles A. Sanders Legacy Fund of the FNIH.

Read more at fnih.org/SandersPartnership.

CONVENING LEADERS TO CHART THE PATH TO PROGRESS
Next-generation breakthrough therapies require the construction of diverse alliances to identify the best ways to treat and serve patients worldwide. The FNIH specializes in convening key stakeholders from wide-ranging sectors to identify and tackle scientific challenges and knowledge gaps to propel research forward.

As one example, in September, the FNIH hosted the 11th International Forum on Rheumatoid Arthritis (RA): Pathogenesis and Emerging Therapeutic Strategies, or IFRA 2019. The meeting brought together major scientific leaders from industry and academia in Asia, Europe and the United States, including NIH Director Dr. Francis Collins. The group represented a global consortium with a shared collective goal of accelerating discovery and innovation in RA.

A chief outcome of the meeting was laying the foundation for a future International RA Collaborative Network building on the work of existing initiatives, such as the Accelerating Medicines Partnership for RA and lupus, to foster transformative studies and facilitate international collaboration. An article published in the *Annals of the Rheumatic Diseases* lays out the session’s overarching themes and provides a vision for the path forward.

Trailblazer Prize finalists Ami S. Bhatt, M.D., Ph.D.; James Kochenderfer, M.D.; Evan Macosko, M.D., Ph.D.; and Giovanni Traverso, M.B., B.Chir, Ph.D. at the FNIH Annual Fall Board Dinner.
BREAKTHROUGH APPROACHES BRING US ONE STEP CLOSER TO PRACTICAL SOLUTIONS TO HEALTH CHALLENGES FACED BY PEOPLE WORLDWIDE.
DEVELOPING BETTER VACCINES TO PREVENT TUBERCULOSIS WORLDWIDE

The global burden of tuberculosis (TB) is staggering: Around the world, one person infected with the disease dies every 18 seconds. According to the World Health Organization, TB is “the leading cause of death from a single infectious agent,” killing more people worldwide than HIV/AIDS or any other infectious disease. The need for new approaches to target and end the global TB epidemic is clear.

The only existing vaccine for TB, called Bacillus Calmette Guerin (BCG), is commonly administered to newborns. While the vaccine confers important health protections to infants and young children, its effects wear off over time, so that adolescents and adults may not be safeguarded against the disease.

In 2019, the FNIH announced the TB Vaccine project, funded through a grant from the Bill & Melinda Gates Foundation. Researchers at NIAID and the University of Pittsburgh are setting out to study whether the way the BCG vaccine is administered could make a difference in its long-term protective effects. The vaccine is currently delivered intradermally, or injected into the skin. Could intravenous delivery, or injection directly into the vein, better prevent TB?

The researchers will test intravenous injection in animal models to see if that technique better activates white blood cells that can help to trigger a powerful, long-lasting immune response. Using cutting-edge immune cell analysis, radiologic imaging, microbiology and pathology analyses, the scientists will learn more about the biological mechanisms of protection. Ultimately, the project’s goal is to use the study’s findings to inform a TB vaccine design of the future, bringing the world that much closer to solving this global public health affliction.

Read more at fnih.org/TBvaccine.

FILLING A NEED OF THE NATION’S LEADING RESEARCH CENTER

At the NIH Clinical Center — the nation's premier hospital solely devoted to clinical investigation — patients are considered "active partners in medical discovery," participating in experimental trials carried out by NIH institutes to receive treatment for their conditions and ultimately benefit scientific progress. The extensive list of research breakthroughs coming out of the NIH Clinical Center includes the first cures for childhood leukemia and Hodgkin’s disease using chemotherapy, the first blood tests for AIDS and hepatitis, and the first gene therapy, to name just a few. To support such resource-intensive endeavors, the FNIH established the Clinical Center In-Kind Drug Donation Program to donate pharmaceuticals to the NIH Clinical Center. The program, which has provided nearly $16 million in drugs and therapeutics to the NIH since 2008, was supported in 2019 by a major gift from Horizon Therapeutics plc. “The generosity of the program has been a major boon to our patients and our program,” says Dr. Steven Holland, Director, Division of Intramural Research at NIAID.

To learn more, visit fnih.org/DrugDonation.

USING CUTTING-EDGE IMMUNE CELL ANALYSIS, RADIOLOGIC IMAGING, MICROBIOLOGY AND PATHOLOGY ANALYSES, THE SCIENTISTS WILL LEARN MORE ABOUT THE BIOLOGICAL MECHANISMS OF PROTECTION.
THANK YOU TO OUR DONORS

The FNIH acknowledges and thanks each of its donors, whether they are an individual, not-for-profit, foundation or corporation. Their generosity ensures that the FNIH has the essential resources required to advance a wide variety of pace-setting and innovative research, training and education initiatives. While unrestricted gifts allow the flexibility to use donations where they are urgently needed, restricted gifts serve a specific area of research. Other donors choose to establish funds and endowments to pay tribute to their loved ones. Gifts identified with a $ reflect multi-year pledge commitments and cash received. Please note the FNIH's Statutory Report to Congress reports private-sector contributions by donor name, exact gift amount and purpose of each gift. This report can be found at fnih.org/about/financials.
WAYS TO GIVE

SPOTLIGHT ON: THE FNIH FUTURES FUND

Virtually all of the funds raised by the FNIH support specific projects to advance crucial biomedical research goals. During public health emergencies, or to seed new discoveries, the Foundation is called upon to assist the NIH in its response to new and emerging priorities. In such cases, the ability to access flexible funding is of paramount importance. In 2018, the Board of Directors established the Foundation’s first endowment, the FNIH Futures Fund. Supported by an inaugural gift from Dr. Steven and Jann Paul, the endowment marks a turning point in the Foundation’s history, providing the flexibility to advance critical research projects and drive the innovation that promotes life-saving biomedical progress.

To learn more about the FNIH Futures Fund, please contact Robert Balthaser at rbalthaser@fnih.org.

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Learn more at fnih.org/PartnersSociety.

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For questions regarding bequests or estate planning visit fnih.org/PlannedGiving and join others who include the FNIH in their estate plans at fnih.org/LegacySociety.

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Learn more about gifts to honor someone special at fnih.org/TributeGiving.

FUNDS AND ENDOWMENTS:
Contribute to or establish a fund or endowment that advances research in a particular area of interest by searching FNIH programs at fnih.org/Programs.

RESEARCH PROGRAMS:
Find a specific research program to donate to at fnih.org/ProgramFundraising.

“WE ARE PROUD TO SUPPORT THE FNIH FUTURES FUND, ALLOWING THE FNIH TO MORE NIMBLY RESPOND TO NEW CHALLENGES AND ENSURING ITS ABILITY TO CONTINUE CREATING A HEALTHIER FUTURE FOR ALL OF US.”

Dr. Steven and Jann Paul
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<th>Donors</th>
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<tr>
<td>$15,000,000+</td>
<td>Bill &amp; Melinda Gates Foundation[^14] §</td>
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# Financial Highlights

## Revenue and Support

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contributions</td>
<td>$49,827,480</td>
<td>$58,261,723</td>
</tr>
<tr>
<td>Grants</td>
<td>220,665</td>
<td>116,338</td>
</tr>
<tr>
<td>Administrative costs</td>
<td>(50,000)</td>
<td>64,723</td>
</tr>
<tr>
<td>Transfers from NIH</td>
<td>500,000</td>
<td>2,000,000*</td>
</tr>
<tr>
<td>Investment income</td>
<td>5,197,124</td>
<td>917,698</td>
</tr>
<tr>
<td>In-kind contributions</td>
<td>270,780</td>
<td>256,859</td>
</tr>
<tr>
<td>Donated services</td>
<td>50,000</td>
<td>60,000</td>
</tr>
<tr>
<td>Fundraising event</td>
<td>401,000</td>
<td>368,156</td>
</tr>
<tr>
<td><strong>Total revenue and support</strong></td>
<td><strong>$56,417,049</strong></td>
<td><strong>$62,045,497</strong></td>
</tr>
</tbody>
</table>

## Expenses and Changes in Net Assets

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program services</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fellowships and training programs</td>
<td>$939,134</td>
<td>$1,074,653</td>
</tr>
<tr>
<td>Memorials, awards and events</td>
<td>575,570</td>
<td>486,093</td>
</tr>
<tr>
<td>Capital projects</td>
<td>60,340</td>
<td>852,380</td>
</tr>
<tr>
<td>Research programs</td>
<td>59,558,215</td>
<td>34,264,962</td>
</tr>
<tr>
<td><strong>Total program services</strong></td>
<td><strong>$61,133,259</strong></td>
<td><strong>$36,678,088</strong></td>
</tr>
</tbody>
</table>

| Supporting services  |               |               |
| Management and general | $6,123,632   | $5,436,683    |
| Fundraising          | 552,675       | 515,538       |
| **Total supporting services** | **$6,676,307** | **$5,952,221** |
| **Total expenses**   | **$67,809,566** | **$42,630,309** |
| Change in net assets | $(11,392,517) | $19,415,188   |
| Net assets beginning of year | $129,902,807 | $110,487,619 |
| **Net assets at end of year** | **$118,510,290** | **$129,902,807** |

*This figure reflects transfers from NIH for 2018 and 2019 federal government fiscal years.*
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