[TRANSFER TO TRANSFORM]

Guiding Ideas to Solutions

OFFICE OF TECHNOLOGY COMMERCIALIZATION | 2024

NATIONWIDE CHILDREN'S®

When your child needs a hospital, everything matters.

A HOSPITAL ENVIRONMENT IS A FERTILE ECOSYSTEM FOR NEW IDEAS. INNOVATORS FROM EVERY CORNER OF THE ORGANIZATION — FROM SURGEONS, DOCTORS AND NURSES TO RESEARCH STAFF — HAVE UNIQUE PERSPECTIVES ON WHAT CAN HELP A PATIENT, OR A FELLOW CLINICIAN OR SCIENTIST.

MESSAGE FROM LEADERSHIP: MAKING OUR MARK

At Nationwide Children's Hospital, we understand the importance of translating innovative work beyond our walls and into the world. New technologies drive economic development in our local, national and global ecosystem and most importantly, improve pediatric care. The Office of Technology Commercialization exists to ensure that the necessary partnerships are in place to execute this important function.

In 2012, our office had three employees. Flash forward to 2024 and we have grown into a sophisticated office of 20 full-time professionals specializing in intellectual property management, licensing, start-up support, federal compliance, project management and strategic alliances. According to the annual Association of University Technology Managers Licensing Survey, Nationwide Children's Hospital's commercialization revenue has ranked in the top 40 among all reporting U.S. universities and academic research institutions for the last five years, and in the top 15 in both 2017 and 2021. This activity has also resulted in 28 out-licensed technologies that are currently in active clinical trials, as well as the regulatory approval and commercialization of two novel therapeutics and two novel medical devices. During this time, 21 start-up companies launched from Nationwide Children's are either still active or have been acquired by a strategic partner.

Indeed, the intellectual property developed here is plentiful and continuing to advance. Additionally, we have invested in a full-service regulatory services department for Food and Drug Administration (FDA) filings and interactions, created a pre-license Technology Development Fund for proof of concept and prototyping which has deployed more than $2.8 million in funding, and deployed more than $15 million in pre-seed and seed funding to Nationwide Children's start-up companies. Our commercialization track record and the experience of building and successfully functionalizing the infrastructure described above speak to the fitness of our institution to support the mission of translational impact on the lives of patients.

As we begin 2024, and I begin my 13th year with the organization, I am tremendously proud of what we have accomplished so far. I am pleased with our organization's leadership that had, and continues to have, the vision to support commercialization activity as materially important to the life cycle of impactful innovation. I am delighted with the individuals on our team, and beyond, who have executed so well. I am proud to have been a small part of it, and daily I am excited by all of it. As you read the following pages of this report, I hope that you too will feel that same energy.

Matthew McFarland, RPh, PhD
Vice President of Commercialization and Industry Relations | Nationwide Children's Hospital

LEADERSHIP

Learn more about our team:

Matthew McFarland, RPh, PhD, *Vice President of Commercialization and Industry Relations*

Matthew.McFarland@NationwideChildrens.org | (614) 722-2701

Matthew McFarland, RPh, PhD, joined Nationwide Children's Hospital in 2012. During his tenure, the OTC has experienced an increase in annual deal flow by 900%. Novel deal structures with licensing partners have also brought additional development resources to the institution. Dr. McFarland has been key to the recruitment and establishment of industrial partners in Columbus, Ohio and brokering strategic partnerships for Nationwide Children's.

Susannah Wolman, *Operations and Business Manager*

Susannah.Wolman@NationwideChildrens.org | (614) 355-2818

Susannah Wolman joined Nationwide Children's in 2016. She manages the team of professionals who handle disclosures, federal reporting and other reporting efforts, intellectual property, marketing efforts, events, internal and external gap funding, and the financial transactions of the office.

Margaret Barkett, PhD, *Director of Licensing*

Margaret.Barkett@NationwideChildrens.org | (614) 355-2957

Margaret Barkett, PhD, joined Nationwide Children's in 2010. Dr. Barkett was instrumental in negotiating deals that led to the hospital's first gene therapy startups. She currently oversees the OTC's licensing efforts, managing an integrated team of licensing professionals, agreements specialists and an alliance manager.

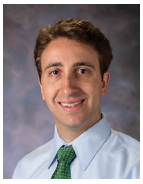
Matthew McFarland, RPh, PhD
Vice President of Commercialization and Industry Relations

Margaret Barkett, PhD
Director of Licensing

Susannah Wolman
Operations and Business Manager

Andrew Corris, PharmD, JD
Senior Licensing Associate
Andrew.Corris@NationwideChildrens.org
(614) 355-1604

Jocelyn Eidahl, PhD
Senior Licensing Associate
Jocelyn.Eidahl@NationwideChildrens.org
(614) 355-2848



Kyle Murrah, PhD
Senior Licensing Associate
Kyle.Murrah@NationwideChildrens.org
(614) 355-4551

Ellen Zalucha, PhD
Licensing Associate
Ellen.Zalucha@NationwideChildrens.org
(614) 355-1663

Joseph Mills, PhD
Licensing Associate
Joseph.Mills@NationwideChildrens.org
(614) 355-0244

Matthew Moscato
Alliance Manager
Matthew.Moscato@NationwideChildrens.org
(614) 355-8784

Akua Ofori
Agreements Assistant
Akua.Ofori@NationwideChildrens.org
(614) 722-6044

Ben Johns
Agreements Assistant
Ben.Johns@NationwideChildrens.org
(614) 722-0771

James Carter, JD
Legal Services Contracts Administrator
James.Carter@NationwideChildrens.org
(614) 355-0244

David Bellamy-Bise
Senior Disclosure and Compliance Coordinator
David.Bellamy-Bise@NationwideChildrens.org
(614) 722-4163

Geena Licata
Senior Intellectual Property Coordinator
Geena.Licata@NationwideChildrens.org
(614) 355-4302

Patricia Lige, MBA
Finance Coordinator
Patricia.Lige@NationwideChildrens.org
(614) 722-6231

Deborah Lewis
Senior Intellectual Property Coordinator
Deborah.Lewis@NationwideChildrens.org
(614) 355-4569

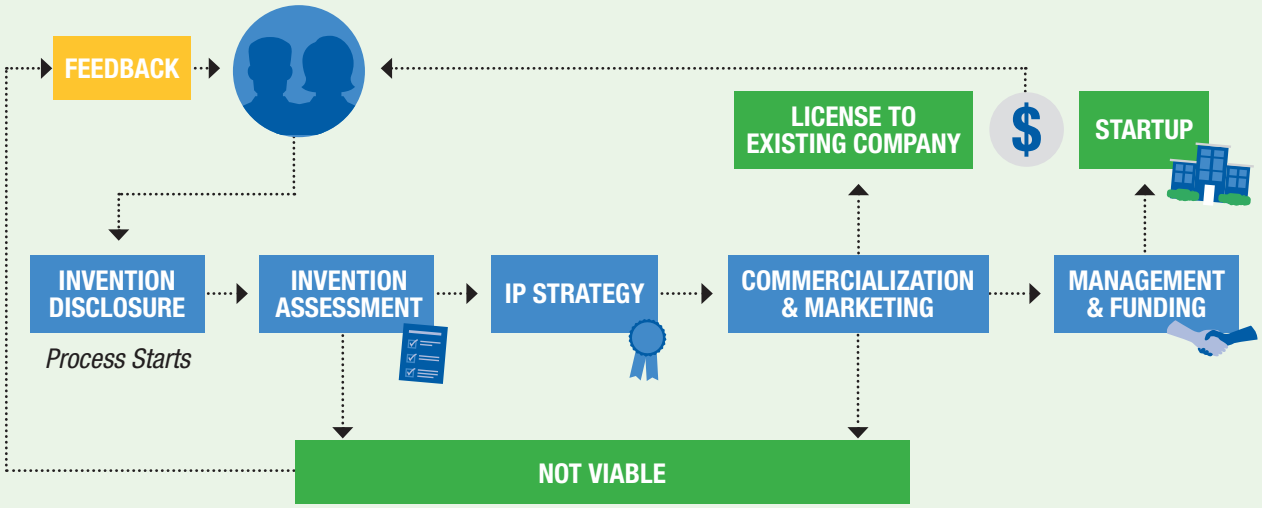
Andrea Strang
Intellectual Property Coordinator
Andrea.Strang@NationwideChildrens.org
(614) 722-6411

John Westerfield II, MSBC
Marketing and Business Coordinator
John.Westerfield@NationwideChildrens.org
(614) 355-1850

OUR MISSION: GUIDING IDEAS TO SOLUTIONS

The Office of Technology Commercialization at Nationwide Children's facilitates the partnering of innovative technology and translational infrastructure with industry to benefit patient care, our community and the general public.

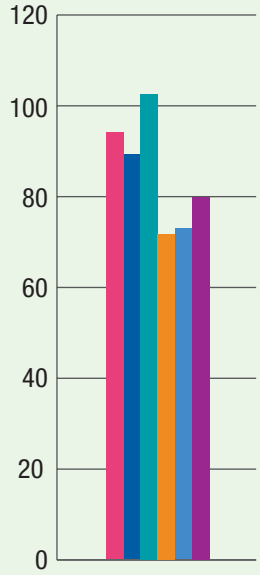
OUR PROCESS



The Nationwide Children's Hospital Office of Technology Commercialization offers expertise in technology transfer, facilitating partnerships between inventors and industry to bring discoveries to patients, clinicians and scientists around the world. Our resourceful team guides inventors and partners through complex processes with creative solutions.

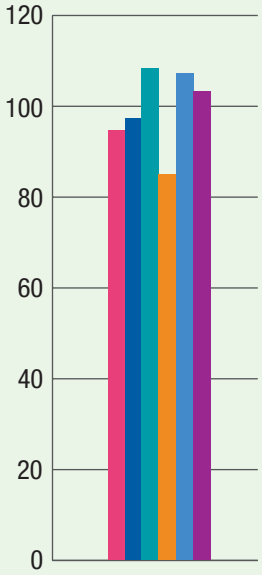
OUR OUTPUT

DISCLOSURES

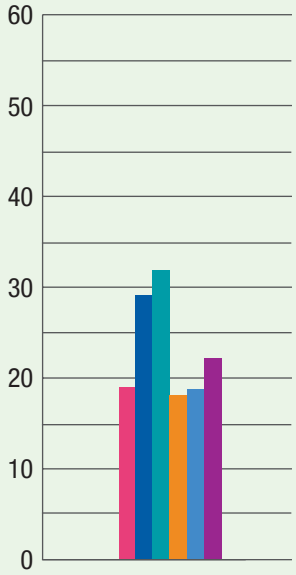


CONTRIBUTORS

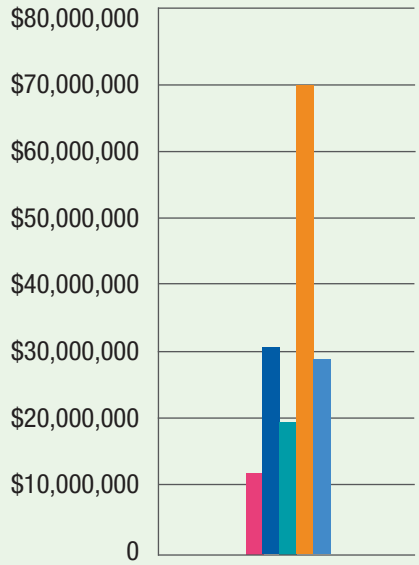
A contributor is any Nationwide Children's faculty or staff member who submitted one or more invention disclosures.



NEW DEALS

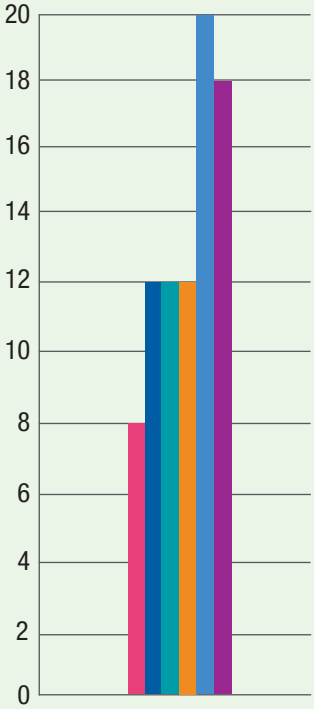


TOTAL REVENUE*

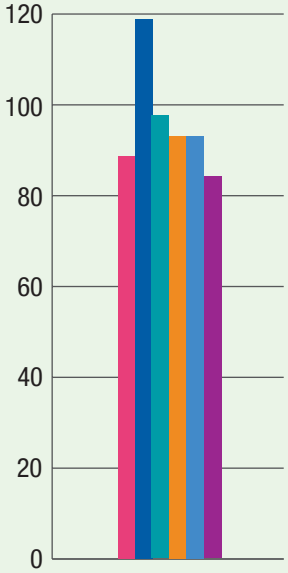


**2023 revenue unavailable at time of print.*

U.S. PATENTS ISSUED



U.S. PATENT APPLICATIONS FILED



**Per AUTM definitions, Patent Cooperation Treaties are included in these metrics.*

2023 INNOVATOR OF THE YEAR

Jerry Mendell, MD

Duchenne Muscular Dystrophy (DMD), a severe form of muscular dystrophy caused by a mutation in the DMD gene and resulting in a lack of the dystrophin protein, leads to muscle weakness and atrophy. DMD is an X-linked condition and, as such, typically affects boys. In 1969, Jerry Mendell, MD, was working at the National Institute of Neurological Disorders and Stroke (NINDS) when he saw his first patient with DMD, igniting his passion to develop new treatments for patients with neuromuscular diseases.

"This is what I've devoted my life to; since I began investigating gene therapy as a potential treatment for children with neuromuscular disorders, it's been my dream to develop a gene therapy for DMD," Dr. Mendell says.

In 1999, Dr. Mendell performed the first in-human clinical trial using AAV for gene transfer to skeletal muscle for LGMD2D/R3. Today, he has been involved in two of the first five AAV-based gene therapies approved by the Food and Drug Administration (FDA)

Dr. Mendell was the principal investigator in the study of the gene transfer clinical trial for spinal muscular atrophy type 1, which led to the development of Zolgensma®, the first systemically delivered gene therapy to receive FDA approval in 2019. In June 2023, the FDA announced the accelerated approval of SRP-9001/ELEVIDYS for children 4-5 years old with Duchenne muscular dystrophy.

Over his career, Dr. Mendell has been involved with 18 different Nationwide Children's technologies and is listed on 408 patent applications resulting in 60 issued patents to date.

Dr. Mendell was elected to the National Academy of Medicine in 2021, and he was the first recipient of the American Society for Gene and Cell Therapy (ASGCT)'s Jerry Mendell Translational Medicine Award. He has published more than 400 articles and authored books on skeletal muscle disease, peripheral nerve disorders, and gene therapy.

Prior to his retirement in October 2023, Dr. Mendell was an attending neurologist, principal investigator, and the Dwight E. Peters and Juanita R. Curran Endowed Chair in Pediatric Research at Nationwide Children's and professor of Pediatrics and Neurology at The Ohio State University. He is a senior advisor in the Center for Gene Therapy in the Abigail Wexner Research Institute at Nationwide Children's and an emeritus professor of Pediatrics at The Ohio State University. Dr. Mendell has also joined Sarepta Therapeutics as a senior advisor, placing him in a position that will help move gene therapy for neuromuscular disease to its full potential.

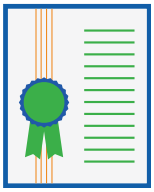
Over his career, Dr. Mendell's work has supported Nationwide Children's growth and success, including:

18 DIFFERENT TECHNOLOGIES

10 TECHNOLOGIES LICENSED

408 PATENT APPLICATIONS

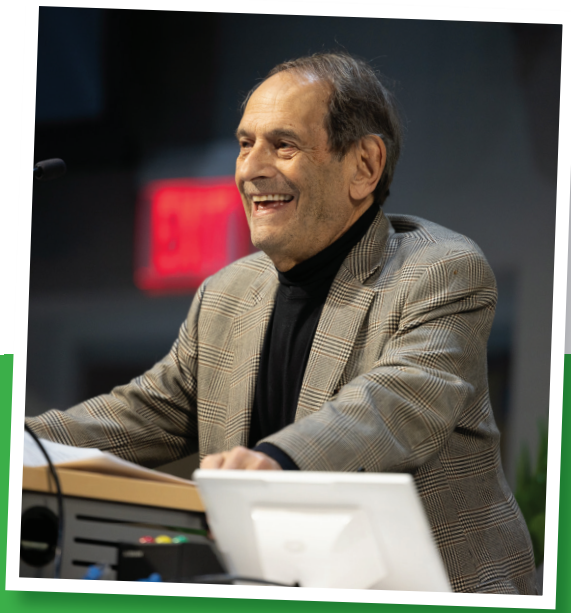
60 PATENTS ISSUED



Left to right: Dennis R. Durbin, MD, MSCE, president of the Abigail Wexner Research Institute (AWRI) at Nationwide Children's Hospital, Jerry R. Mendell, MD, senior advisor in the Center for Gene Therapy in AWRI, Matthew McFarland, RPh, PhD, director of the Office of Technology Commercialization in AWRI.

INNOVATION

Dr. Mendell was recognized by AWRI leadership for his achievements at the OTC's Excellence in Innovation reception in November 2023.



Scan the code to learn more about Dr. Mendell and his research.

Patents are an integral component of technology commercialization. Nationwide Children's innovators who have successfully patented new inventions in the United States between October 2022 and September 2023 include:

Michael T. Bailey, PhD
Issued Patent — 11,497,780

Lauren O. Bakaletz, PhD
Issued Patents — 11,746,136, 11,690,892, 11,684,673, 11,564,982, 11,629,182, 11,497,780

Gail E. Besner, MD
Issued Patent — 11,497,780

Christopher Breuer, MD
Issued Patent — 11,541,149

Dawn Chandler, PhD
Issued Patent — 11,566,247

Steven D. Goodman, PhD
Issued Patents — 11,746,136, 11,690,892, 11,684,673, 11,564,982, 11,629,182, 11,497,780, 11,484,479

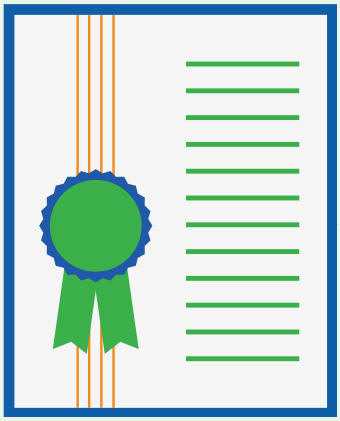
Syed-Rehan Hussain PhD
Issued Patent — 11,492,614

Jerry R. Mendell, MD
Issued Patents — 11,723,986, 11,534,501, 11,446,396

Mark Peeples, PhD
Issued Patent — 11,739,348

Ryan Roberts, MD, PhD
Issued Patent — 11,660,291

Lauren Warren, PhD
Issued Patent — 11,484,479



Affiliations

Nationwide Children's is a sustaining member of Rev1 Ventures, an organization created to accelerate innovation, business growth, job creation and prosperity in the 15-county region of central Ohio. Rev1 Ventures works to create new companies, strengthen existing businesses, open doors to technology resources and support the attraction and retention of technology-based businesses.

Scan the QR code to learn more about Rev1 Ventures.

Ohio Life Sciences

As Ohio's bioscience, health and life sciences membership and development organization, Ohio Life Sciences (formerly BioOhio) is focused on convening the state's outstanding assets to accelerate the growth of its globally competitive bioscience ecosystem. High on this list of assets is pediatric research, in which Nationwide Children's exhibits excellence every day. Nationwide Children's has been an OLS Leadership member for nearly 25 years.

Scan the QR code to learn more about OLS.

OhioX is Ohio's statewide technology and innovation partnership dedicated to helping make Ohio a leading tech hub. OhioX powers connections, tells impactful stories, and advocates for growth on behalf of Ohio technology and innovation. As a founding member of OhioX, Nationwide Children's joins industry-leading organizations across Ohio in building the future.

Scan the QR code to learn more about OhioX.

HELP TODAY'S DISCOVERIES BECOME TOMORROW'S INNOVATIONS

Our portfolio of over 200 available technologies developed by our innovative researchers and clinicians is diverse and ever-growing. They span a wide array of research fields and categories of market applications and range from early-stage innovations to market-ready products.

TYPES OF INNOVATIONS

Biomarkers: Detect and measure normal biological processes, pathogenic processes or responses to interventions.

End User Innovations: Improve clinical or business practices and patient outcomes with improved/ novel medical devices and software.

Gene Therapies: Deliver new genetic material to replace impaired or harmful genetic material to treat various conditions.

Therapeutics: Prevent or treat diseases.

Tissue Engineering Innovations: Combine scaffolding, seeded cells and biologically active molecules into functional tissues, allowing a patient's own cells to be used to grow new tissue or organs for repair.

Research and Clinical Tools: Enhance therapeutic or research activities.

Technology Showcase

Each March, the OTC highlights new inventions and startup companies generated through innovation at Nationwide Children's Hospital through its flagship Technology Showcase event.

In addition to presentations about impactful Nationwide Children's technologies, the 2024 event featured a panel discussion with industry experts discussing emerging trends and opportunities in pediatric medical device development.

To learn more and find the right licensing opportunity for you, visit NationwideChildrens.org/AvailableTechnologies and access our highlighted technologies database.

CAYUSE INVENTIONS

- Search our entire catalog of licensable technologies by disease, disorder or technology type.
- Learn more about the technologies available in each category and the inventors behind them.
- Connect with the licensing associates who manage our technologies.

To license a technology or get assistance with your search, please call **(614) 355-1850** or email Tech.Commercialization@NationwideChildrens.org.

Not ready to begin the licensing process? Our team can help you stay informed about all new and available technologies developed at Nationwide Children's.

View the recording and register for the next event to learn more about our new technologies that are available to license and the inventions already transforming care: **NationwideChildrens.org/OTC-Events**

Innovative Approaches to Patient Care

Tuberous sclerosis complex (TSC) is a devastating genetic disease that affects nearly 1 in every 5,500 newborns and approximately 2 million people worldwide. The disease is characterized by the formation of nonmalignant tumors throughout multiple organs, predominantly the brain. Typically diagnosed in infants and young children, who frequently suffer morbidity due to neurologic complications, TSC is also one of the leading genetic causes of syndromic autism. Of various neurologic symptoms, severe and frequent seizures are among the most debilitating and potentially fatal.

"There is currently no cure for TSC. In the past decade, we've learned that seizure control is critical because it is a major determinant of cognitive outcomes in patients. However, even with some of the most potent antiseizure medications, only about 50% of patients have clinically relevant reductions in seizure frequency," explains Mark Hester, PhD, a principal investigator in the Steve and Cindy Rasmussen Institute for Genomic Medicine at Nationwide Children's. "When patients no longer respond to these antiseizure medications, resective surgery is an option, but this approach only offers a 50% chance of long-term seizure freedom."

The most severe form of TSC, Type 2, is caused by mutations in the TSC2 gene, which encodes a protein called tuberin. With other proteins, tuberin forms a protein complex that regulates a critical cell signaling pathway involved in cell growth and metabolism.

Dr. Hester and colleagues have developed and are now testing a gene replacement therapy for TSC Type 2. The gene therapy uses adeno-associated viruses (AAVs) to deliver a functional version of the gene to affected cells. AAVs have been used in FDA-approved gene replacement therapies for treatment of spinal muscular atrophy and certain patients with Duchenne muscular dystrophy, both developed at Nationwide Children's.

Mark Hester, PhD, a principal investigator in the Steve and Cindy Rasmussen Institute for Genomic Medicine at Nationwide Children's

"AAV vectors are safe, non-integrative, highly efficacious for gene delivery, and provide a potentially one-time curative treatment for patients," says Craig McElroy,

"One thing that is different about this gene therapy opportunity is the tremendous amount of effort that was put into creating the replacement gene."

– Andrew Corris, PharmD, JD, senior licensing associate in Nationwide Children's Office of Technology Commercialization

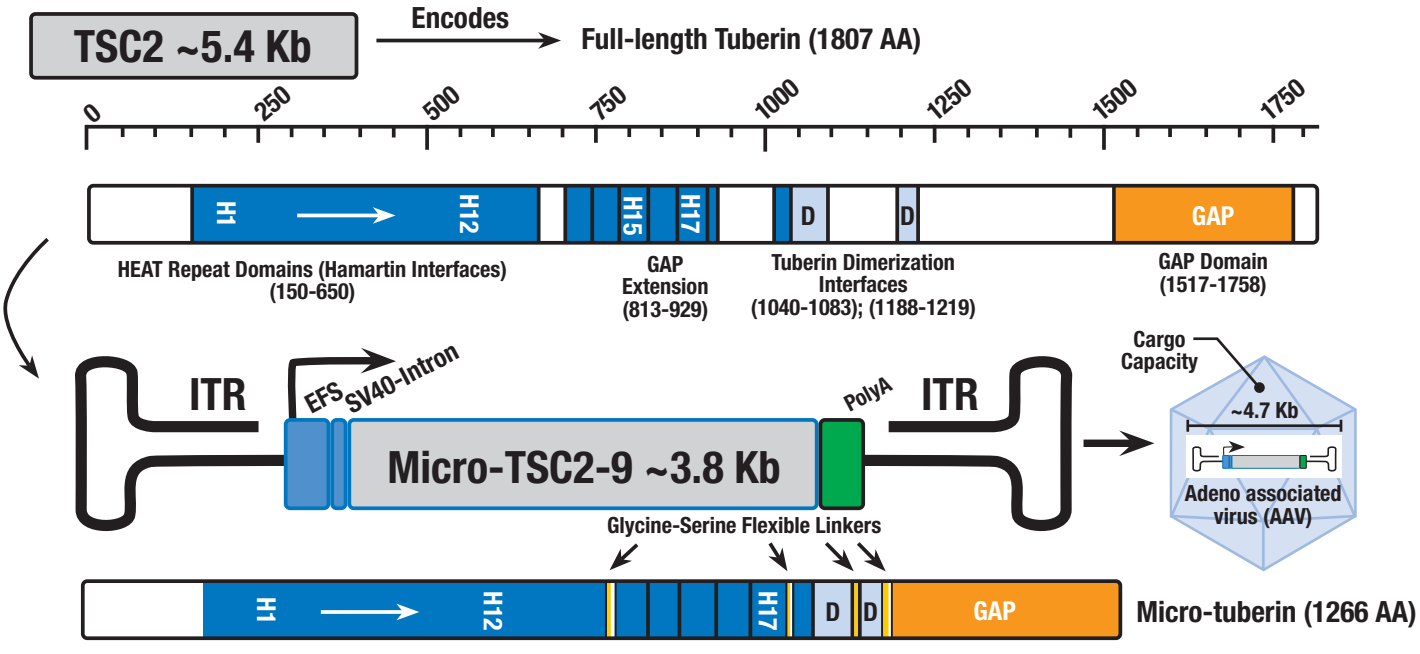
PhD, vice president of Pharmacokinetics at InfinixBio, an Ohio-based contract research organization. "However, these vectors have a limited cargo capacity, and the *TSC2* gene is too large to be packaged into current vectors."

To overcome this, the team devised a strategy to replace the faulty *TSC2* gene with a miniaturized version that when encoded still retains nearly the exact structure and function of the full-length Tuberin protein.

"TSC" causes severe seizures, autism, brain tumors and other organ complications, such as kidney disease. As clinicians, we currently treat symptoms, but do not have a way to treat the underlying cause. The innovative approach Dr. Hester and his colleagues are taking with TSC2 has great potential to enable us to treat the whole person in a revolutionary way," says Adam Ostendorf, MD, pediatric neurologist and medical director of the Epilepsy Surgery Program at Nationwide Children's.

"One thing that is different about this gene therapy opportunity is the tremendous amount of effort that was put into creating the replacement gene," shares Andrew Corris, PharmD, JD, a senior licensing associate in Nationwide Children's Office of Technology Commercialization. "It was done in a very informed way that we typically would not see with other products. That gives me a lot of confidence in the potential efficacy of this product."

The researchers have begun preliminarily testing several of their "micro-Tuberin" candidates and in vitro efficacy studies have shown robust proof-of-concept for further advancement.



The team has generated a novel, miniaturized form of TSC2, which was developed using rational protein engineering and protein structure prediction validation. Micro-tuberin can be packaged into AAV and delivered directly to the central nervous system (CNS) or systemically for a whole-body gene replacement therapy.

Gene Therapy for the Masses?

Long-lived financial and logistical hurdles make bringing new gene therapy products to market a major challenge. To help bring more of these medical miracles to fruition, experts across industry, regulatory review, science and medicine have begun to problem solve together.

With the approval of the gene therapy Kymriah® (tisagenlecleucel) in 2017, the Food and Drug Administration (FDA) kicked off a new era in medical therapy in the United States.

This watershed moment stoked an already raging fire in the cell and gene therapy industry. In the time since Kymriah's entry to the market, another 33 cell and gene therapies have received approval, and more than 300 investigational new drug (IND) applications for gene therapies are now filed with the FDA each year.

As promising as these figures are, the fact remains that gene therapies are phenomenally expensive to develop and manufacture. On average, it costs nearly $2 billion to bring a new cell or gene therapy to market — a downside passed along to patients and payers, with the costliest therapy to date, Hemgenix®, priced at about $3.5 million per dose.

How can development and dosing at these costs be sustainable? Despite their tremendous potential to treat and cure disease, small markets and sky-high production costs leave many potential therapies unexplored, and thus, many patients untreated.

Thankfully, the field of gene therapy is full of experts pursuing solutions to the economic problems plaguing the industry. Together, they are actively seeking opportunities for efficiency in development, manufacturing,

Easton Reed, 11, is able to ride his bike with his siblings five years after receiving a gene therapy in a clinical trial at Nationwide Children's Hospital to treat Duchenne muscular dystrophy. The therapy that helped preserve Easton's muscle function is now approved by the FDA, bringing hope for a healthier future to thousands living with the disease.

regulation and post-market policies to make it possible for more life-saving gene therapies to reach patients.

An Uphill Battle

The majority of the drug development market relies on medium- or large-scale production of medications purchased and used repeatedly by large numbers of people, which enables developers to recoup the costs of drug development and cover losses from failed segments of the portfolio. As science advances to the point of being able to treat hundreds of rare and ultra-rare diseases through single-dose therapies, a new framework for drug creation, production and reimbursement must emerge.

"We have licensed several gene therapy programs that have been returned to us, because companies don't see them as commercially viable — there are so few patients that it doesn't make strategic sense to proceed," says Margaret Barkett, PhD, director of licensing for the Office of Technology Commercialization at Nationwide Children's Hospital. Her team licensed two of the current FDA-approved gene therapies. "It's a pity because often you have the IND, you have the gene therapy product manufactured and you're ready to go, you just don't have the funds to move it through the rest of the process."

With gene therapy, the risk of each investment is amplified; potential market size (and thus potential profit) is typically small, but the research and development required to generate the therapy is at least as expensive as for any other drug.

These concerns become even more challenging when the patient population is so limited that the therapies cannot realistically or ethically be evaluated in comparison to natural history or placebo groups. The result is often insufficient or underwhelming data, even in situations with promising initial studies. This endangers investments, puts patients at risk, and forces regulatory agencies into difficult decisions between potential risks and rewards for patients.

Obtaining the necessary upfront capital is, therefore, an understandable challenge. If the drug makes it through trials at all, profit must be squeezed from only a few dozen doses per year, at a price tag that often raises objections from payers and the public. In addition, many gene therapies struggle to break into foreign markets due to high costs, further limiting market potential to very few high-income countries.

For companies manufacturing a therapy that treats only a few patients per year, covering overhead of running the facility for the remainder of the year is also problematic. Facilities that are not diversified and able to produce products for multiple therapies struggle to maintain the expensive staff and equipment. At least two gene therapy companies closed in autumn 2023 alone.

"Most small foundations and even researchers often severely underestimate what it will cost to get a gene therapy to trial," says Kevin Flanigan, MD, director of the Center for Gene Therapy in the Abigail Wexner Research Institute at Nationwide Children's, and the

"Most small foundations and even researchers often severely underestimate what it will cost to get a gene therapy to trial."

– Kevin Flanigan, MD, director of the Center for Gene Therapy in the Abigail Wexner Research Institute at Nationwide Children's

Five-year-old Gideon Griffiths received the first infusion of ELEVIDYS (SRP-9001) at Nationwide Children's after its accelerated FDA approval in June 2023.

principal investigator behind successful gene therapy programs for Duchenne muscular dystrophy and Sanfilippo syndrome.

"We try to be very, very clear about the escalating costs at different stages of a viral vector program," says Dr. Flanigan. "Component One is discovery and lead candidate optimization work. Component Two triggers another big expense: the IND-enabling toxicology and dose-escalating work. Then, Component Three brings another order-of-magnitude change in costs: making the doses to give to an actual human."

In cases where production does proceed to pivotal clinical trials or to market, companies face similar set-up costs regardless of the size of the batch being made. Whether the goal is to produce 10 doses or 10,000, purification processes, quality controls and verification of materials' safety take similar time and money. Clinical good manufacturing processing (cGMP) facilities must also maintain other aspects of the facility regardless of batch size, such as single-use technologies, recycled air to avoid cross-contamination, and regulatory requirements.

Regulatory complexity only adds to the expense, requiring analysis and review of each source material and step of the process — for each batch. The tests often deplete large portions of the manufactured product, leaving significantly less for dosing. When upfront investments allow, some companies opt to develop clinical-quality batches straight from the beginning of preclinical work in the hopes that a single batch will get them to market.

Regulatory agencies, researchers and contract development and manufacturing organizations (CDMOs) have been working to address some of the key causes of slow regulatory review: bespoke processes, variable controls and production methods, expensive materials and high-touch manufacturing techniques.

Regulatory Red Tape and Silver Linings

Regulatory challenges arise in part from the fact that cell and gene therapies are still the new kids on the

pharmaceutical block. Each therapy, viral vector and production process is evaluated individually, even if significant portions of the process or source materials have already been reviewed and found sufficient for approved therapies.

"Prior to COVID, the FDA felt the process was the product, so if there was a change in cell lines or media, it meant starting over," says Wade Macedone, CEO of Andelyn Biosciences, a CDMO working from concept to commercialization in viral vector production. "There is now concerted effort from the industry to show that the science and analytics are established — to address fear of the unknown that was driving costs and hindering speed and innovation. In the last 12 months or so, they've been starting to let industry solve problems with analytics, much more efficiently than by going back to the clinic."

The FDA is working toward a more rapid and flexible review process across the board. Ideally, they want the field of gene therapy to get to a platform model — a shared system within a given viral vector, with the same production processes. Familiar, shared materials and processes then demand less attention with each new drug application. This "plug and chug" approach would subject just the new genetic payload and the clinical trial data to full scrutiny, rather than the entire operation.

"Honestly, if we're going to try to get through thousands of diseases, we're not going to get there the way we're doing it right now," said Peter Marks, MD, PhD, director of the Center for Biologics Evaluation and Research at the FDA, at the 2023 Technology Showcase sponsored by the Office of Technology Commercialization at Nationwide Children's. "We need to figure out ways to leverage the things in gene therapy that facilitate us moving from one gene therapy to another. In other words, we need to stop treating them like small molecules or protein therapeutics."

To this end, the Bespoke Gene Therapy Consortium (BGTC), funded by a private-public partnership called the Accelerating Medicines Program through the NIH, FDA and other organizations, funds platform innovations that can streamline gene therapy development. The program aims to create a protocol "playbook" that other researchers can use to develop gene therapies with less difficulty and expense.

The National Institute of Neurological Disorders and Stroke (NINDS) also funds Innovation Grants to Nurture Initial Translational Efforts (IGNITE), providing resources for neurotherapeutic agent characterization and in vivo efficacy studies. From there, the Ultra-rare Gene-based Therapy (URGenT) program funds promising therapies for ultra-rare monogenic neurological diseases in late preclinical through clinical trials.

To help streamline review and development efforts, the FDA announced the Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program. It will test a new way of communicating with drug developers, aiming to speed up the feedback and enable faster, more financially feasible development by reducing rework and costly waiting periods.

Most gene therapies under development also qualify for privileged FDA statuses, such as Priority Review. The review status comes as a "voucher" and can save 4+ months over standard review timelines. These can be sold for $100 million or more and offer another creative tactic some companies have used to fund gene therapy development.

"From a licensing perspective, we are trying to figure out ways to broker deals with partners to mitigate risk and share the cost of bringing them to patients."

– Margaret Barkett, PhD, director of licensing for the Office of Technology Commercialization at Nationwide Children's Hospital

Dr. Marks is also hopeful that global regulatory convergence can streamline the regulatory review and approval process for gene therapy candidates moving forward.

Finding Financial Answers

Gene therapy isn't just focused on rare and ultra-rare diseases. There are many companies in the race to develop gene therapies for larger markets — everything from obesity and alcoholism to cancer have been considered candidates for novel gene therapies.

These indications, which have much larger annual markets than monogenic diseases, have the potential to fund discovery and development costs for ultra-rare gene therapies by making it easier to justify the expense of viral vector production.

"As we're able to scale and meet needs of larger indications, that's going to be a paradigm shift," says Andrew Moreo, head of process development, plasmid and viral vector core facilities for Andelyn Biosciences. "The first time we get an indication that can cover a lot of people, that will start to offset costs."

Risk-sharing agreements between academic institutions, manufacturers and funding organizations may also help ease the upfront burden and financial risk of producing these costly therapies for trials or markets. These approaches ensure no single investor takes a debilitating hit when a therapy fails.

"From a licensing perspective, we are trying to figure out ways to broker deals with partners to mitigate risk and share the cost of bringing these gene therapies to patients," says Dr. Barkett.

Once a therapy does hit the market, paying for them to actually be delivered to patients is yet another challenge. Creative solutions are emerging for this problem as well, such as pooled insurance provider accounts that can be used to cover therapy for individuals in need, regardless of their insurer.

Thinking globally, lower-income countries could be an even better potential market than other high-income nations, both for patient benefit and for making it more financially feasible to run sizeable batches of gene therapy products that can be put to good use across a global population.

"In many parts of the world, people die of treatable diseases because they cannot get access to ongoing

At the age of 5, Connor Stoll was the first patient to receive the gene therapy in a clinical trial at Nationwide Children's Hospital to treat Duchenne muscular dystrophy. The treatment has helped him retain his muscle strength and prevent disease progression for more than five years.

care," says Macedone. "A one-and-done therapeutic dose could spare them a lifetime of morbidity or even early death due to lack of supportive care."

With advancements in manufacturing and trends toward regulatory standardization, breakthroughs should bring with them a major rebound in capital investments — which will translate to greater access to gene therapy for many patients in need.

Developing Manufacturing and Scientific Solutions

Automation and simplification of the gene therapy production process may offer significant cost savings, similar to the hard-won cost-saving advancements achieved in the manufacturing of biologic therapies.

"Consolidating work into facilities such as Andelyn that can handle multiple products, increase standardization of processes and platforms and spread costs of

goods across multiple different products can make the whole process more sustainable," says Moreo. "We're about 10 years behind the monoclonal antibody industry; once they settled on best practices for manufacturing and purification, that's when you saw it take off and get efficient."

Some of the latest innovations on the market include end-to-end robotic manufacturing, wherein customizable controls can be leveraged for the entire process to be completed in a clean room with no human intervention. Automation can also improve reproducibility and generate ongoing, informative data during live production, allowing teams to make adjustments as needed to reduce batch-to-batch variability.

Improvements in manufacturing efficiency would be all for naught, however, if therapies cannot prove their value in preclinical models and clinical trials.

Animal models for rare monogenic disorders are not readily available for most diseases. Furthermore, models developed with only limited transplants of human cells do not allow researchers to understand the specificity of a potential therapy, or its off-target effects. Although some new models for neurodegenerative diseases have been discovered, they can be costly and challenging to study.

More customizable emerging options include organoids, which are 3D tissue models of diverse cell populations derived from adult stem cells to mimic the cellular environment of a particular organ. These offer additional data about disease mechanisms as well as the potential safety and efficacy of a gene therapy approaching clinical trials. Understanding the therapy's impact in human organoids helps bridge the gap between animal models or cell line studies and human trials. In time, patient-specific organoids treated with gene therapy could even be transplanted into patients to improve function of affected organs.

Even more exciting, body-on-a-chip models combine multiple different organoids (such as liver, heart, lungs, kidney and more) and additional induced pluripotent stem cells in a universal media. These are contained in a microfluidic platform with biophysical and chemical cues and stressors that mimic the body's environment. This approach may allow scientists to understand how a gene therapy affects multiple organs and body tissues, as well as immunogenicity, genomic integration and biodistribution.

Other advancements for adeno-associated viral vector-based therapies in particular aim to improve the likelihood of therapy success and safety by improving screening for potential immunogenicity, studying off-target effects, immunostaining to determine tissue tropism, examine risks for genomic integration and improve tissue-specific toxicity knowledge.

Moreo explains that, in viral-mediated gene therapy, the challenges stem from having many different biologic products.

"Way down the road, we can expect things to evolve to nonviral or even synthetic, virus-like nanoparticles," he says. "These not only carry a genetic payload but also target specific areas or organs, and that on-target specificity will be key."

While these advances improve preclinical progress and data-gathering opportunities, little can be done about limited populations for clinical trials, which inherently limits knowledge about a therapy's safety and efficacy.

"Prior to COVID, the FDA felt the process was the product, so if there was a change in cell lines or media, it meant starting over. There is now a concerted effort from the industry to show that the science and analytics are established.

– Wade Macedone, CEO of Andelyn Biosciences

To address this, the FDA has begun to issue advice on common challenges to gene therapy, including the draft guidance "Demonstrating Substantial Evidence of Effectiveness Based on One Adequate and Well-Controlled Clinical Investigation and Confirmatory Evidence," which is expected to be the first of many guidance documents advising more standardized and acceptable approaches to small-population gene therapy development.

While statistical methods and careful preclinical investigations do not fully replace large-scale phase 3 trials, they attempt to make the best of a challenging situation by enabling approval and therapy access to desperate patients, despite data limitations.

The Coming Gene Therapy Revolution

With several decades of lessons under the belts of researchers, manufacturers and investors, gene therapy is primed to transform the future of medical therapy for millions of individuals.

Significant safety improvements allow new therapies to proactively avoid many concerns present in prior iterations. Researchers now more clearly understand what developing a therapy entails, and more realistic expectations can be given to investors and hopeful families or funding organizations.

Nationwide Children's Center for Gene Therapy recently established a Personalized Gene Therapy Committee, for example, to help align expectations and facilitate communication between researchers and investors — often private foundations, advocacy organizations or even individuals — as a new gene therapy is pursued. It bases the communication and review process on the fount of knowledge accumulated by researchers and technology transfer specialists during the hospital's numerous gene therapy trials and licensing successes. The group also discusses opportunities to ensure access to research for populations without wealthy donors or active patient advocacy groups.

As the field faces its current challenges, the future is bright.

"Industry leaders are coming to the table to find solutions to the problem [of high costs]," says Macedone. "The community wants it, the government wants it, the scientists want it. Funding will come back, disease populations that can be treated will get larger, and we will get to the point that it's as easy to get gene therapy as it is to take a dose of aspirin. It's decades, if not a generation, off. But we'll get there."

More therapies will be developed and approved. More manufacturing and regulatory solutions will emerge. And more patients *will* be treated.

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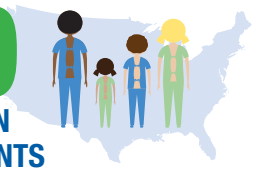
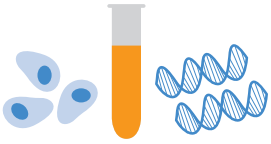
GENE THERAPY BY THE NUMBERS

30 MILLION
U.S. PATIENTS
with 7,000 known rare/ultra-rare diseases



85%
of rare/ultra-rare diseases are monogenic

$2 BILLION
to bring a new cell or gene therapy to market



33
FDA-approved cell and gene therapies

10-20 / year
expected cell and gene therapy product approvals by **2025**

$20.4 BILLION
projected average annual spending on gene therapies, 2023-2024

94,696 PATIENTS
expected to be treated with gene therapies in **2025**

1.09 million CUMULATIVE PATIENTS
expected to be treated with gene therapies in **2034**

This data comes from the citations listed with the gene therapy story

Hear Me Read: Novel Technology Approach to Reading Skills for Children With Impaired Hearing

For children who are deaf or have impaired hearing, access to sound through tools like hearing aids, cochlear implants and/or intensive speech therapy is critical for developing speech and literacy.

"The challenges faced are not the same as those an adult faces," says Prashant Malhotra, MD, surgeon in the Department of Pediatric Otolaryngology and Hearing Program at Nationwide Children's Hospital and associate professor at The Ohio State University College of Medicine. "The impact of hearing loss on a child who has so much development to undergo is far greater."

Anand Satyapriya, MD, an anesthesiologist at OhioHealth Riverside Methodist Hospital, thought about these things as he began planning how best to help his newborn son, who was diagnosed with hearing impairment shortly after birth.

"I started to think about this idea that would help my son and other children with hearing impairment navigate the therapy process more efficiently," Dr. Satyapriya says. "I realized I hadn't the faintest idea of how or where to begin. That's when I approached my son's cochlear implant surgeon — Prashant Malhotra."

Hear Me Read is a first-of-its-kind digital storybook innovation targeted toward helping children with hearing impairment develop speech and literacy skills. It is a software application, currently available in iOS and web access planned for 2024, enabling parents and speech-language pathologists (SLP) to partner together to help children who are hearing impaired achieve reading, speech and language goals. Utilizing storybook learning, the goal is to further stimulate language development at home to supplement office-based speech therapy.

"The major issue when dealing with children who are hearing impaired is that you are dealing with different parts of speech on a weekly basis," says Dr. Malhotra. "That's the beauty of our app. It's all customizable for what the child needs to work on, and it's all done in an evidence-based manner utilizing proven methods of speech therapy." Additionally, this is an all-in-one application for different parts of speech that the child needs to work on. Digital Story Therapies allows the parents and SLP to collaborate by providing trackable progress and in-person sessions to be more targeted.

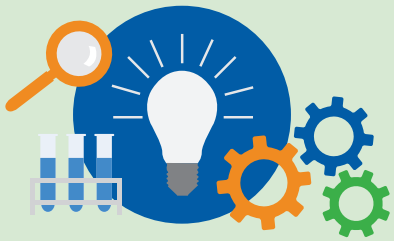
"The OTC is thrilled for the accomplishments Digital Story Therapies has achieved so far! The DST team is working diligently and innovatively, and the results show as they continue to have success in funding and partnerships. We look forward to Digital Story Therapies' further development in the next year as they continue to build out and expand their application and utilize their partnership with Highlights for Children to improve the lives of children who are impacted by hearing loss."

– Ellen Zalucha, PhD, Licensing Associate at Nationwide Children's Hospital

With the guidance of the Office of Technology Commercialization at Nationwide Children's, and collaboration from experts in speech therapy, user experience and technology development, the team secured several rounds of grant funding to develop the idea into a usable tool. Through these funding mechanisms and a passion for improving the lives of children impacted by hearing loss, Drs. Malhotra and Satyapriya co-founded Digital Story Therapies, Inc.

The startup recently received Phase II funding from the Ohio Third Frontier Technology Validation and Start-up Fund (TVSF) in October 2023. With this funding, Digital Story Therapies Inc., will continue developing the technology and incorporating digital storybooks from their partnership with Highlights for Children. The team is also planning a multi-entity pilot starting in July 2024.

"Hear Me Read [Digital Story Therapies] has a lot of potential as a tool for conducting literacy research in children who are deaf/hard of hearing," Dr. Malhotra adds. "With it, we may begin to study the underlying processes of why or how reading interventions work in children who are deaf/hard of hearing. This will enable us to develop new interventions for better outcomes."



INVENTORS:

Janelle Huefner, MA CCC-SLP, A/AOGPE
Nationwide Children's Hospital,
parent of a child with dyslexia

Shana Lucius, MA CCC-SLP, LSLS
Certified Auditory-Verbal Therapist,
Nationwide Children's Hospital

John Luna, MFA
Research Information Solutions & Innovation,
Nationwide Children's Hospital

Prashant Malhotra, MD
Nationwide Children's Hospital,
The Ohio State University

Anand Satyapriya, MD
OhioHealth Riverside Methodist,
parent of child who is deaf/hard of hearing

A New Catalyst for Pediatric Device Development

In September 2023, the Food and Drug Administration (FDA) announced a $6.95 million grant to be distributed over five years to create a new consortium led by investigators from Nationwide Children's Hospital, The Ohio State University, Cleveland Clinic Children's and Cincinnati Children's Hospital Medical Center to help increase the number of pediatric medical devices across the nation.

"The opportunity to lead the charge in our region toward the development of medical devices for pediatric patients is incredibly exciting," says Cory Criss, MD, co-principal investigator and chief operating officer of the consortium, and pediatric surgeon at Nationwide Children's. "It was a massive effort and really highlights the amazing talent and expertise that we have to offer in the region."

The Midwest Pediatric Device Consortium (MPDC) includes Nationwide Children's, The Ohio State University Wexner Medical Center, Cleveland Clinic Children's Hospital, Cincinnati Children's Hospital, Ohio Life Sciences and Rev1 Ventures. Many other regional health care systems, academic institutions, and industry partners are also committed. The MPDC will work to conceptualize, prototype, test, manufacture, market and commercialize pediatric medical devices.

"While there are plenty of medical and surgical devices on the market available for patients, it's important to remember that children are not little adults and are underserved in this space. They require equipment catered to them, making pediatric device development vitally important," says Matthew McFarland, RPh, PhD, chief technical officer of the consortium and vice president of commercialization and industry relations at Nationwide Children's. "We are thrilled to be collaborating across institutions in order to bring more pediatric-focused devices from bench to bedside, to benefit patient outcomes."

"As home to several of the leading hospitals and universities in the country, as well as a vibrant medical technology infrastructure, Ohio is an ideal space to establish this new consortium," says David Eckmann, PhD, MD, co-principal investigator, chief executive officer of the consortium and founding director of the Center for Medical and Engineering Innovation (CMEI) at The Ohio State University College of Medicine. "This is an excellent step toward improving patient care not only throughout Ohio but across the country."

(LEFT)
David Eckmann, MD, PhD, co-principal investigator, chief executive officer of MPDC and founding director of the Center for Medical and Engineering Innovation (CMEI) at The Ohio State University College of Medicine.

(RIGHT)
Cory Criss, MD, co-principal investigator and chief operating officer of MPDC and pediatric surgeon at Nationwide Children's.

Meet Daphne©, a ChatBot for Pediatric Health Care

Machine learning and artificial intelligence (AI) have exploded across the worlds of marketing and commerce in recent years. At Nationwide Children's, clinicians and researchers are focusing on how AI and related technologies can be used to reduce clinician workloads and improve patient outcomes.

Emre Sezgin, PhD, principal investigator in the Center for Biobehavioral Health at Nationwide Children's, leads the Intelligent Futures Research Lab. He and his team are working to build a healthier future for all children and families using intelligent methods and approaches to scientific research and development.

Dr. Sezgin believes AI can help improve the health system itself if applied strategically. His Chatbot for Social Needs project, funded by the Health Resources and Services Administration (HRSA), uses conversational AI to address families' social needs, to contribute to medical records with patients' self-reported health information and communicate with providers.

Dr. Sezgin's team has been working diligently to test and deploy conversational AI applications for social needs identified proactively by patients or by clinicians during visits.

The project relies on a technology chatbot (named Daphne©), which uses AI-based conversation tools to communicate with natural language and intelligently provide highly relevant, service-oriented resources for patients and families.

"Daphne is iteratively designed by our team in the light of multidisciplinary stakeholders' feedback, including primary care clinicians, nurses, social workers, researchers, family advocates and community health workers. It does social needs screening and shares personalized resources based on family needs. It also guides families on how to access the resources," Dr. Sezgin says.

The team is currently conducting real-world testing with families with the help of the Primary Care Research Network and Primary Care Network at Nationwide Children's. In collaboration with Micah Skeens, PhD, APRN, FAAN, the team received INSPIRE grant funding to expand the project toward addressing the social needs of families who have children with cancer, including the creation of a module to screen mental well-being and provide behavioral interventions.

Emre Sezgin, PhD, principal investigator in the Center for Biobehavioral Health at Nationwide Children's leads the Intelligent Futures Research Lab.

"Providers can gain a more complete understanding of a patient's needs, preferences and social determinants of health by utilizing insights from chatbots like Daphne," says Dr. Sezgin.

Several Nationwide Children's-based teams are studying applications of models, such as GPT-3 and GPT-4, with the goal of building useful applications for the medical world and investigating how to operationalize such tools in compliance with rules, regulations and other ethical standards.

"Technological advancements in health care, particularly in natural language processing, have the potential to revolutionize the way physicians and patients interact, paving the way for a more personalized, efficient and effective health care experience," says Dr. Sezgin.

IN GOOD COMPANY

Dozens of startups, which have been critical to advancing new, early-stage therapies to the point of FDA approval, commercial viability and even global distribution, have launched since the Office of Technology Commercialization was formed in 2008. One such startup, Andelyn Biosciences, an affiliate company dedicated to the manufacture of gene therapy products for biotechnology and pharmaceutical industries, has enabled Nationwide Children's to be one of the only pediatric hospitals in the world that can offer gene therapy clinical trials for infants and children.

As Nationwide Children's innovators connect with entrepreneurial partners to launch new ventures, the OTC seamlessly guides them every step of the way.

Learn more about our startups.

Abeona THERAPEUTICS
Working together to find a cure.

avexis

CLARAMETYX biosciences

Andelyn BIOSCIENCES
Reliably Expert. Purposefully Driven.

CELENEX

deep lens

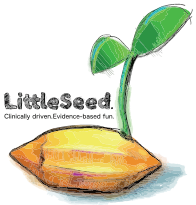
ARMATUSBIO

Cellula
MRCAR-T for solid tumor

ENTVantage DX

"We are thrilled to see the number of startups based on Nationwide Children's Hospital's technology grow each year, expanding on our diverse portfolio of innovations in gene and cell therapy, therapeutics, medical devices and digital health."

– Margaret Barkett, PhD, Office of Technology Commercialization Director of Licensing



Nationwide Children's is a preeminent leader in innovative pediatric health care — a place that pushes the envelope to improve the lives of children everywhere.

In 2021, Nationwide Children's announced the most ambitious strategic plan in its 129-year history: *Leading the Journey to Best Outcomes for Children Everywhere*, a five-year $3.3 billion commitment to transform health outcomes for all children. At the heart of this plan is a focus on integrating and investing in the highest-quality clinical care and cutting-edge research.

Cultivating an organization where research drives clinical care and clinical care drives research ensures children receive the most advanced therapies possible for their conditions. It also brings together bright minds from every corner of the organization dedicated to solving the problems affecting pediatric health.

More than 1,000 faculty work in over 100 subspecialties and 16 research centers. Researchers make discoveries about disease processes and potential therapeutic agents. Clinicians invent devices to address challenges they face in everyday practice. Many doctors, nurses, surgeons and scientists didn't begin their careers expecting to be inventors, but they're all driven by the desire to improve delivery and outcomes, and they all have a hand in innovation.

Luckily, there's no business experience needed. The Office of Technology Commercialization helps creative employees translate novel discoveries to the bedside and bring new ideas to fruition and to market by walking them through every step of the process — from patent searches and prototypes to licensing or launching startups.

More than ever, Nationwide Children's innovators are driving the future of pediatric care.

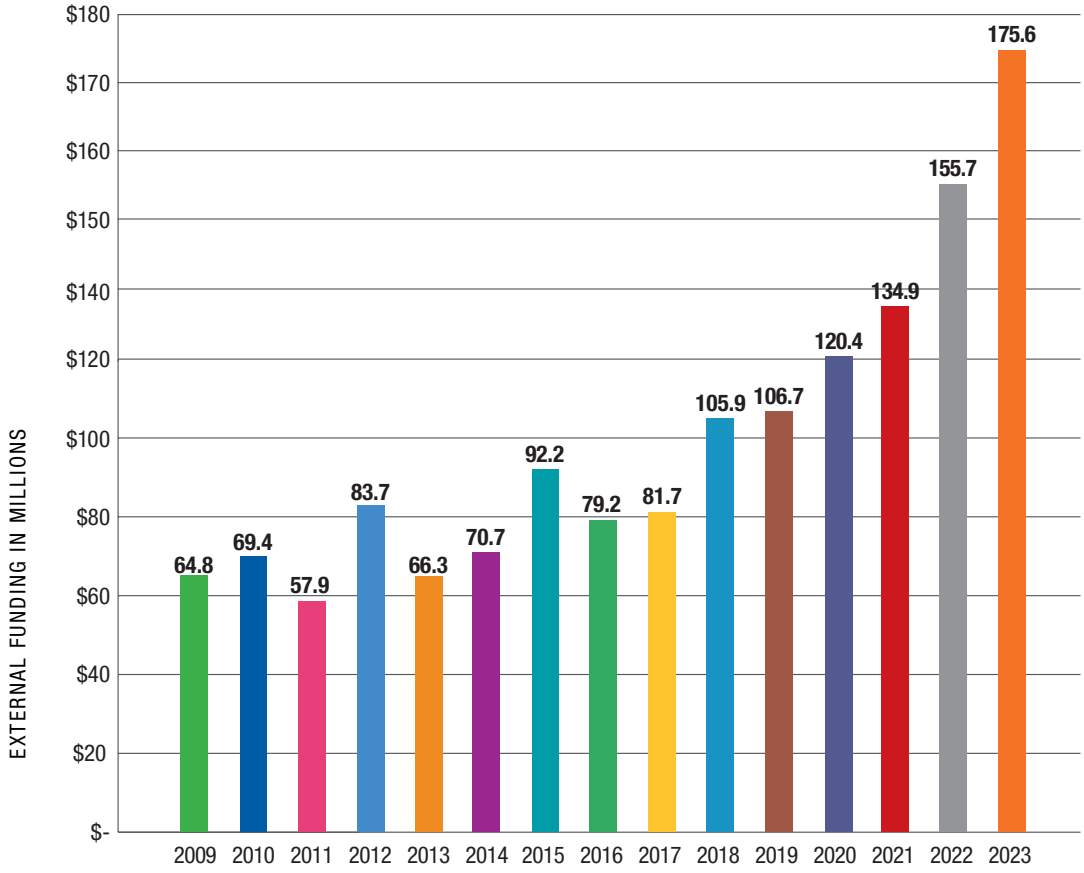
Learn more about the innovative clinical and research programs across Nationwide Children's and the unique ways they're working together in the 2022-2023 Annual Report.

RESEARCH CENTERS OF EMPHASIS

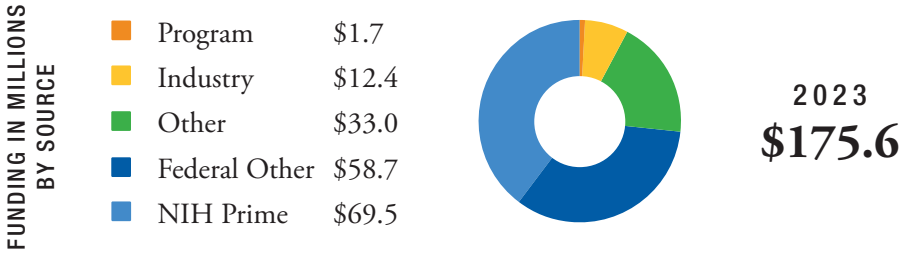
Areas of research in the Abigail Wexner Research Institute at Nationwide Children's transcend traditional academic boundaries, which facilitates interdisciplinary team science and catalyzes discovery.

- Biopathology Center
- Center for Biobehavioral Health
- Center for Cardiovascular Research
- Center for Child Health Equity and Outcomes Research
- Center for Childhood Cancer Research
- Center for Clinical and Translational Research
- Center for Gene Therapy
- Center for Injury Research and Policy
- Center for Microbial Pathogenesis
- Center for Perinatal Research
- Center for Regenerative Medicine
- Center for Suicide Prevention and Research
- Center for Vaccines and Immunity
- Institute for Mental and Behavioral Health Research
- Kidney and Urinary Tract Center
- Steve and Cindy Rasmussen Institute for Genomic Medicine

RESEARCH GROWTH AT NATIONWIDE CHILDREN'S



2023 EXTERNAL AWARDS



RESEARCH BY THE NUMBERS

	2021	2022	2023
Principal Investigators*	223	249	264
Research Fellows	92	78	93
Graduate Students	57	61	68
Employees	1460	1613	1815
Publications	1633	1740	1820

**Includes faculty from the Abigail Wexner Research Institute and faculty from Nationwide Children's Hospital with $50,000 or more in research funding support.*

OUR SPACE: WORLD-CLASS FACILITIES FOR LIFE-CHANGING DISCOVERY

RESEARCH FACILITY HIGHLIGHTS

Research Building I (the Wexner Institute for Pediatric Research) contains 136,580 square feet of dedicated research space contiguous with Nationwide Children's clinical facilities.

Research Building II provides 164,016 square feet of additional space, including a 200-seat amphitheater, that is also contiguous with the clinical facilities.

Research Building III is 238,914 square feet and includes a 75-seat conference facility. Research Building III is certified by the U.S. Green Building Council Leadership in Energy and Environmental Design (LEED) program for sustainable building design.

Research Building IV is a companion to Research Building III, pushing Nationwide Children's dedicated research space to span more than 800,000 square feet across campus.

MAIN CAMPUS HIGHLIGHTS

- 1,563,577 square feet of inpatient space.
- 681,415 square feet of outpatient space.
- 761,816 square feet of education and support areas.
- Largest neonatal network and provider of inpatient pediatric surgeries in the United States.*

**Most recent data from CHA-member pediatric hospitals, based on highest number of ICU beds and inpatient surgeries.*

APPROVED PRODUCTS IMPACTING PATIENTS

FDA-APPROVED GENE THERAPIES

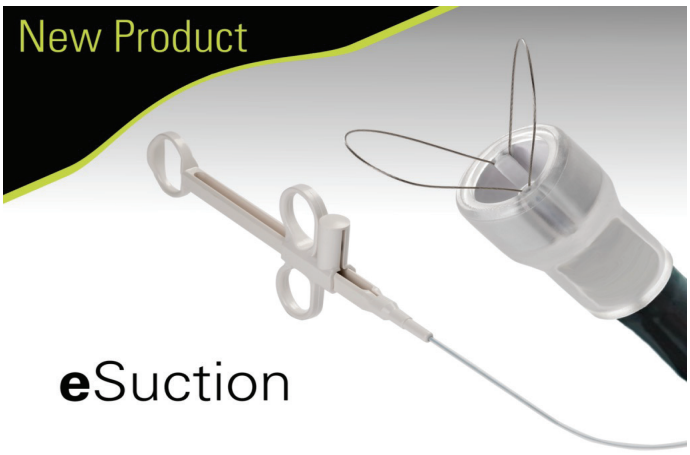
zolgensma®
(onasemnogene abeparvovec-xioi)
suspension for intravenous infusion

For patients with
Spinal Muscular Atrophy (SMA)

Elevidys
delandistrogene moxeparvovec-rokl
suspension for intravenous infusion

For patients with
Duchenne Muscular Dystrophy (DMD)

MEDICAL DEVICES ON THE MARKET



eSuction

Comfort Collar

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NOTES

Nationwide Children's Hospital
700 Children's Drive
Columbus, Ohio 43205-2696
NationwideChildrens.org

CONTACT US:

Office of Technology Commercialization
Nationwide Children's Hospital
700 Children's Drive | Columbus, Ohio 43205

Phone: (614) 355-2818 | Fax: (614) 722-2716
Email: **Tech.Commercialization@NationwideChildrens.org**
LinkedIn: **LinkedIn.com/showcase/-office-of-technology-commercialization**

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NATIONWIDE CHILDREN'S®

When your child needs a hospital, everything matters.

W1017178