[TRANSFER TO TRANSFORM]

Guiding Ideas to Solutions



OFFICE OF TECHNOLOGY COMMERCIALIZATION | 2025





"Each year the Transfer to Transform publication is an opportunity for our organization to memorialize and celebrate our institution's growth, success and impact as an innovation engine. We have several stakeholders that look forward to its publication, and we are truly honored to have this platform to showcase our activity.

- Dennis Durbin, MD, MSCE, president, Abigail Wexner Research Institute

MESSAGE FROM LEADERSHIP: MAKING OUR MARK

t Nationwide Children's Hospital, we are deeply committed to translating cutting-edge research into real-world solutions that benefit children and families. Over the years, we have fostered a vibrant ecosystem where our clinicians, researchers and industry partners work together to bring breakthrough technologies from the laboratory, and bedside, to the marketplace. This collaboration accelerates the development of novel treatments, devices and therapies, ensuring that they reach the patients who need them the most.

Our commercialization and technology transfer activities are a key pillar of this mission. By identifying high-potential innovations and forging strategic partnerships with industry leaders, we aim to bridge the gap between groundbreaking scientific discoveries and their widespread application in health care. Through our dedicated team, we manage intellectual property, support commercialization efforts and guide entrepreneurs and startups through the complex journey of bringing their innovations to fruition.

We believe that the future of pediatric care hinges on fostering a strong culture of innovation, collaboration and shared purpose. As the health care landscape continues to evolve, we are excited about the opportunities ahead and are eager to expand our impact through continued partnerships and knowledge exchange. As you read the following pages of this report, I hope it is clear to you the commitment that Nationwide Children's Hospital has made to impacting the lives of children everywhere through its innovation and commercialization efforts. I am truly honored to be a part of this team, and humbled daily by the amazing individuals that drive our commercialization engine.

Dennis Durbin, MD, MSCE President, Abigail Wexner Research Institute Nationwide Children's Hospital Professor and Vice-Chair for Research Department of Pediatrics, The Ohio State University College of Medicine

LEADERSHIP



Margaret Barkett, PhD, Interim Director of Office of Technology Commercialization and 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.

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.

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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.



The Nationwide Children's 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.

DISCLOSURES 150 120 100 80 60 20 2021 2022 TOTAL **REVENUE*** 25 \$80,000,000 \$70,000,000 \$60,000,000 \$50,000,000 \$40,000,000 \$30,000,000 \$20,000,000 \$10,000,000

*2024 revenue unavailable at time of print.

OUR OUTPUT

CONTRIBUTORS

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









U.S. PATENT APPLICATIONS FILED*



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

NEW DEALS

2024 INNOVATORS OF THE YEAR Scott Harper, PhD, and Paul Martin, PhD

he innovator of the year is selected for their social impact, imagination and partnership. This year's awardees are both principal investigators in the Jerry R. Mendell Center for Gene Therapy. The center's mission is to investigate and employ the use of gene- and cell-based therapeutics for prevention and treatment of human diseases.

Paul Martin, PhD

Dr. Martin has been a principal investigator in the Center for Gene Therapy since 2004. He is also a professor of Pediatrics, Physiology and Cell Biology at The Ohio State University College of Medicine. The Martin Lab focuses on two main research areas: development of novel gene therapies for neuromuscular disorders and identification of functional roles for glycans in muscle and neuromuscular biology.

Dr. Martin is associate director of the National Institutes of Health Center of Research Translation in Muscular Dystrophy Therapeutic Development at Nationwide Children's Hospital. As part of the NIHfunded research program, Dr. Martin's lab has identified particular carbohydrates that, when overexpressed in muscle cells, can prevent muscular dystrophy from occurring in a number of forms of the disease.

Another major focus of Dr. Martin's research is identifying genes that play significant roles in neuromuscular and lysosomal storage disease and then creating gene therapy vectors to effectively deliver a healthy gene or surrogate for the gene back to the diseased area. Recently, through this research, Dr. Martin developed a novel dual gene therapy approach for muscle diseases. These new therapies allow gene correction to inhibit disease while building new muscle mass and strength by expressing a second gene from a single adeno-associated virus (AAV) therapy. These new therapies can reverse pre-existing muscle disease in patients while inhibiting further disease progression.

Some of Dr. Martin's gene therapy programs have been or are in the process of being licensed to a new startup company, Genosera Inc., that Dr. Martin co-founded.

The goal of Genosera is to bring these new gene therapy technologies to patients with neuromuscular or lysosomal storage disorders to improve their overall health.

Dr. Martin has been involved with 13 different Nationwide Children's technologies and is listed on 86 patent applications resulting in 22 issued patents.

Scott Harper, PhD

Scott Harper, PhD, has been a principal investigator at the Center for Gene Therapy since 2007. He is also a professor of Pediatrics at The Ohio State University College of Medicine. Dr. Harper is a standing member of the NIH Neurological Sciences and Disorders B (NSD-B) study section and a member of the Scientific Advisory Board of the Charcot-Marie-Tooth Association (CMTA). He also serves on three committees of the American Society of Gene and Cell Therapy (ASGCT).

Dr. Harper's research at Nationwide Children's focuses on developing AAV based gene therapies to treat neuromuscular and neurological disorders, including muscular dystrophy (FSHD, LGMD1A), peripheral neuropathy (CMT1A, CMT2D, CMT4B3) and dominant epilepsy. His lab has also focused on developing models and studying the pathogenesis of facioscapulohumeral muscular dystrophy (FSHD) and identifying ways to improve AAV vector manufacturing to create a more safe and effective gene therapy.

Dr. Harper has been involved with 45 different Nationwide Children's technologies and is listed on 206 patent applications, which have resulted in 71 issued patents. Some of his portfolio has been licensed to the Nationwide Children's startup company, Armatus Bio, where he also serves as chief scientific advisor. Armatus is focused on moving forward Dr. Harper's gene therapy programs for CMT1A, CMT2D and FSHD.





Patents are an integral component of technology commercialization. Nationwide Children's innovators who have successfully patented new inventions in the United States between October 2023 and September 2024 include:

Lauren O. Bakaletz, PhD Issued Patent No.: 12,048,740

Timothy P. Cripe, MD, PhD Issued Patent No.: 12.037.370

Scott Harper, PhD Issued Patent No.: 11,939,579

Scott Harper, PhD, Sara Coppens and Lindsay Wallace Issued Patent No.: 11,802,291

Left to right: Dennis Durbin (President of the Abigail Wexner Research Institute), Paul Martin, Scott Harper, Tim Robinson (CEO of Nationwide Children's Hospital) and Matt McFarland (Former Vice President of Commercialization and Industry Relations)

Scott Harper, PhD, and Nicolas S. Wein, PhD Issued Patent No.: 12,084,658

Dean Lee, MD, PhD Issued Patent No.: 11.696.927

Nicole F. O'Brien, MD Issued Patent No.: 11,883,230

Zarife Sahenk, MD, PhD Issued Patent No.: 11,926,653

Ohio Ecosystem Partners



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.





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.



Ohio

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.



cincytech

CincyTech is a venture capital firm that invests in innovative founders tackling the world's complex challenges, while transforming ideas into world-class companies.



Ohio Ecosystem Partners



Department of Development

The goal of the Ohio Third Frontier Technology Validation and Start-up Fund (TVSF) is to create greater economic growth in Ohio based on start-up companies that commercialize technologies developed by Ohio institutions of higher education and other Ohio not-for-profit research institutions.



JobsOhio exists to empower world-class corporations, entrepreneuers and talented individuals to build their businesses and careers in Ohio. Their advocacy and investment in partnership with the State enable sustainable growth and a better quality of life for all Ohioans.

JUMPSTART

As a nationally recognized entrepreneur support organization, JumpStart equips tech startups and small businesses with the skills, services and support they need to grow and thrive. They work to ensure every entrepreneur has the resources they need to succeed. Since 2010, more than \$13 billion in economic impact has been generated by startups and small business assisted by JumpStart and their partners.



TechGrowth Ohio is a public-private partnershop composed of the Ohio Third Frontier program (TVSF), Ohio University and the private investment community. TechGrowth Ohio is part of an entrepreneurial ecosystem that includes programs supporting university and regional technology commercialization and small business incubation.



The Ohio Discovery Corridor is an ecosystem that connects the vital innovation districts from Columbus, Cincinnati and Cleveland into a high-powered network of top-notch medical and research facilities, academic institutions and private companies. The district fosters discoveries, patents and startups while attracting STEM talent and providing businesses with essential growth capital.









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HELPING 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. The technologies 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



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.





tissue or organs for repair. **Research and Clinical Tools:** Enhance therapeutic or research

Therapeutics: Prevent or treat

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

diseases.

activities.

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.
- 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.

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.

The 2025 event featured five presentations that highlighted impactful innovations generated from the Abigail Wexner Research Institute at Nationwide Children's and a keynote by David A. Williams, MD, addressing genetic therapy in sickle cell disease.

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

• Learn more about the technologies available in each category and the inventors



Breaking New Ground in Cancer Therapy: Is Vironexis the Future of Immunotherapy?

Nationwide Children's researchers develop a scalable, targeted approach to overcoming cancer's toughest challenges.

espite significant advances in treatments, cancer remains one of the leading causes of death globally. Traditional therapies, while improving patient outcomes, still have limitations — such as the need for frequent dosing, complex and costly manufacturing and severe side effects. These challenges are driving the search for more effective and sustainable solutions.

One of the most promising cancer treatment innovations is gene therapy, which offers a targeted approach to treating cancer cells while minimizing damage to healthy tissue. At the forefront of this innovation is Nationwide Children's Hospital, where researchers have developed a technology that produces an off-the-shelf, single-dose treatment designed to address the shortcomings of current immunotherapies.

"Our approach merges immunology and gene therapy in a way that has not been done before," says Timothy P. Cripe, MD, PhD, chief of the Division of Hematology, Oncology and Blood and Marrow Transplant at Nationwide Children's Hospital and a professor of Pediatrics at The Ohio State University. "Gene therapy is most often used to correct genetic disorders, but here we're taking a different path to deliver safer, more efficient and patient-friendly cancer care."

Dr. Cripe co-founded Vironexis Biotherapeutics, Inc., which has developed the TransJoin[™] technology — a scalable platform that produces targeted T cell cancer treatments. Unlike traditional CAR-T therapies, which are more complex, or bispecific therapies that require prolonged infusions, this one-time treatment provides long-term, consistent cancer cell killing, with fewer adverse side effects, even in metastatic cancers.

"Even though many traditional cancer treatments are highly personalized to the patient, over time, cancer cells can develop resistance to them, leaving patients constantly on edge, fearing relapse," Dr. Cripe says.

The TransJoin[™] technology uses an AAV vector infusion that instructs the liver to produce a bispecific protein, guiding T cells to consistently target and destroy cancer cells. This approach significantly reduces toxicity and provides an effective solution with the potential for sustained remission.

"This single infusion turns the liver into a drug factory that continuously produces and secretes a protein that turns T cells into cancer-killing cells," Dr. Cripe explains. "Essentially, we're creating a sort of sentry to look out for cancer cells and prevent them from spreading or coming back."

The TransJoin[™] technology is applicable across many disease indications, including blood-based cancers, solid tumors and cancer prevention. It requires only a targeted gene of interest. No patient customization is necessary.

"We've created a plug-and-play platform that can take any cancer cell target and slot it in to produce the appropriate protein to kill it," Dr. Cripe says. "It's a whole new paradigm in cancer treatment that avoids both the high cost and many adverse side effects of gene therapy."

The first trial using the TransJoin[™] technology is currently recruiting patients with CD19+ acute lymphoblastic leukemia at several sites across the country. Another trial will be ready for patients with metastatic HER2+ breast and gastric cancers in 2025. Vironexis has built a pipeline of more than ten therapies for a variety of cancers and cancer vaccines.

Scan the OR code to learn more about Vironexis





More Than One REMEDY for Genetic Disorders

How a new approach to correcting heterozygous mutations and other novel techniques for gene editing are transforming the potential to combat disease

he field of gene therapy has had some astounding success in recent years - much of which emerged from labs at Nationwide Children's Hospital — but it has also stumbled over some serious logistical roadblocks.

The majority of candidates don't even make it to clinical trials, often due to practical challenges with development including inaccurate vector delivery, large payload size, inefficient protein production, manufacturing difficulties or inability to administer the therapy to the right cells in the right tissue. Of those that do make it into human trials, off-target effects, inefficacy and unforeseen toxicities have complicated some otherwise promising therapies.

Working With What You've Got

Jerry Mendell, MD, advisor to and now the namesake for the Jerry R. Mendell Center for Gene Therapy at Nationwide Children's, wanted a technology that could distinguish between the good and bad gene in a cell during his time researching therapies for muscular dystrophies. Meisam Naeimi Kararoudi, DVM, PhD, director of the CRISPR/Gene Editing Core at Nationwide Children's, delivered one better: he created a CRISPRbased technique not just to tell them apart, but to get cells to use the good copy as a template to replace the bad copy.

The technology, dubbed REMEDY, is surpassing even their initial expectations.

"REMEDY became an extraordinarily powerful methodology we could use for a lot of different genetic disorders that already have a good copy of a gene in the cell," says Dr. Naeimi Kararoudi, who is also a principal investigator in the Center for Childhood Cancer at the Abigail Wexner Research Institute at Nationwide Children's (AWRI). "It has become the licensing avenue for a lot of our other gene therapy platforms."

He and his colleagues, including Yasemin Sezgin, MS, research associate and lab manager in the CRISPR/

Gene Editing Core, and Allison Bradbury, MS, PhD, principal investigator in the Center for Gene Therapy, have corrected many different mutations, including those causing tuberculoidosis-cerebrospinal dyskinesia (TBCD), cystic fibrosis (CF), Valosin-containing protein (VCP) multisystem proteinopathies (MSP) and numerous other disorders in cell line studies, publishing initial results in *Neurology*, with more to come.

Afrooz Rashnonejad, MSc, PhD, principal investigator in the Center for Gene Therapy at Nationwide Children's, has also had success with REMEDY in her laboratory. Her primary research focuses on adeno-associated virus (AAV)-based gene therapies for Charcot-Marie-Tooth (CMT) disease and ACTA1-related congenital myopathy.

"We are using REMEDY in the lab to edit some of the more common mutations that we see in CMT, and it shows great success on induced pluripotent stem cell lines that can later differentiate to Schwann cells, which are the target cells," Dr. Rashnonejad explains. "We can also package REMEDY components to transfer directly to Schwann cells, and we have successfully edited mutations in the ACTA1 gene using REMEDY."

Cell line studies have advanced to the point that Dr. Rashnonejad will begin in vivo animal models. The work is funded both by grants and the Nationwide Children's Technology Development Fund, which helps investigators launch promising studies until they can be supported exclusively by external funding.

More Than One Horse in the Race

Beyond REMEDY, the researchers at Nationwide Children's are exploring numerous technical approaches to gene therapy.

Another group targeting CMT is the lab of Scott Harper, PhD, principal investigator in the Center for Gene Therapy at Nationwide Children's and a veteran in the field of gene therapy. Dr. Harper had a prominent role in the design and development of early gene therapies for



Duchenne muscular dystrophy, now approved by the Food and Drug Administration (FDA) and marketed as ELEVIDYS. Dr. Harper uses CRISPR to interfere with over-expressed genes that cause CMT and facioscapulohumeral muscular dystrophy (FSHD), namely PMP22 and DUX4, respectively.

"We believe that patients would benefit by reducing these toxic gene levels to a normal range," says Dr. Harper, now also chief scientific advisor of Armatus Bio, which licensed early techniques from Dr. Harper's research in the hopes of developing therapies for CMT and FSHD. "We have developed an approach that uses a natural biological process called RNA interference (RNAi) — a cell's natural way to reduce gene products when they become over-produced. We think it's superior to CRISPR for this application, and that's what we're moving toward in the clinic."

His lab uses engineered microRNA to prompt cells to degrade the genes' messenger RNA before they can be used to create toxic levels of proteins.

"Our two lead gene knockdown therapies are in late preclinical stages," says Dr. Harper. "We've demonstrated proof-of-principle and safety in animal models, and are engaging with the FDA with the intention of translating these therapies to clinical trials."

A Matter of Logistics

Multiple teams in the Center for Gene Therapy, including one led by Zarife Sahenk, MD, PhD, a principal investigator in the center also engaged in CRISPRbased gene therapy for CMT, now share a common goal for advancing these therapies: getting the right vector.

Dr. Zarife's approach involves a gene therapy paradigm using AAV1.NT-3 to deliver nerve regeneration neurotrophin in CMT animal models.

"The problem is that REMEDY and other CRISPRbased gene therapies are still too big to fit in a single AAV vector," explains Dr. Naeimi Kararoudi, who together with colleague Nizar Saad, PhD, principal investigator in the Center for Gene Therapy, won the National Institutes of Health Targeted Challenge for

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the idea of using a novel delivery system for REMEDY to treat progeria. "It is our job to work to make it small enough to fit in one AAV, work with others who can do it, figure out how to use extracellular vesicles for delivery or find a new CRISPR solution so that we can make the therapies as efficient as possible."

The problem of space is particularly important for researchers working on CF. The CFTR gene at fault for CF is very large and has dozens of mutations that can result in disease. This has led Sriram Vaidyanathan, PhD, principal investigator in the Center for Gene Therapy at Nationwide Children's, to explore lipid nanoparticles, multi-component delivery and other solutions for packaging a CF gene therapy.

"The transient delivery of lipid nanoparticles and the

viral genome-cutting nature of CRISPR/Cas therapies both have potential limitations, which is why we thought single-stranded DNA (ssDNA) may be a good solution," Dr. Vaidyanathan says. His recently patented technology chemically modifies ssDNA to improve gene insertion and is described in a recent publication in *Nucleic Acids Research*. "With this method, we can try to edit genes *in vivo* to optimize both delivery and editing, and improve the potential of gene therapy for mass production."

After the delivery vehicle is optimized, Dr. Vaidyanathan has yet another challenge to overcome: method of administration. Patients with CF need durable, highly expressed gene correction in multiple organ systems that have high cell turnover. "When your goal is to make long-lived gene replacement, you are better off targeting stem cell populations," explains Dr. Vaidyanathan.

He and other researchers in the CF gene therapy community are actively working to explore intravenous and other methods for delivery to the right cell populations in the lungs to optimize ongoing therapeutic effects of any gene editing.

Down to the Details

Another matter of logistics already partially overcome is how to reduce off-target effects. Many investigators at Nationwide Children's have so far placed their bets on CRISPR-driven gene editing, and guide techniques that target mutant RNA not found normally in the body.

"It's challenging to target and drug a transcription factor, which is how the PAX3::FOXO1 fusion oncogene functions in rhabdomyosarcoma, especially when both PAX3 and FOXO1 are also found normally in our body," says Genevieve Kendall, PhD, principal investigator in the Center for Childhood Cancer at Nationwide Children's. The PAX3::FOXO1 gene fusion drives these aggressive solid tumors. "If you have significant off-target effects, that's a problem, because these genes are critical for normal development, and we don't want treatment to be detrimental."

When Dr. Kendall began collaborating with Dr. Naeimi Kararoudi to develop therapies for this pediatric sarcoma, they opted to use CRISPR/Cas-13, a newer version of CRISPR that targets messenger RNA. They have generated and provisionally patented guide sequences unique to the PAX3::FOXO1 gene fusion.

"We have one guide that, when tested in PAX3::FOXO1 rhabdomyosarcoma patient-derived cells, causes the cells to completely stop growing, which was exciting to see," says Dr. Kendall. "This data made me think this strategy could be impactful. Next, we'll be testing our CRISPR/Cas13-system in patient-derived xenografts *in vivo* to optimize delivery and assess efficacy."

The goal is always to optimize as many parameters as possible before advancing therapies to the next level. That's why scientists at Nationwide Children's often test numerous constructs, prioritize use of human transgene models and question the norms about how the science can and should be done.

- t, "In principle, CRISPR approaches could be used to treat both CMT1A and FSHD," says Dr. Harper. Dr. Rashnonejad, who developed and tested AAV-based Cas13 gene therapy for FSHD, demonstrated its effectiveness in a mouse model. "Although the CRISPR system worked to initially protect mice from DUX4induced muscle damage, we found that over time, the system stopped working due to an immune response to the bacteria-derived CRISPR proteins," says Dr. Harper.
- The work, currently available as a bioRxiv preprint, will be one of the first to report an immunologic response using CRISPR therapies. To the team, it represents only another technical challenge to overcome — which is standard operating procedure for the folks at Nationwide Children's.
- "Various strategies can be applied to attenuate immune responses to the CRISPR system, including approaches such as engineering Cas proteins to reduce immunogenicity, designing more precise guide RNAs, utilizing tissue-specific promoters and implementing immunomodulation strategies," explains Dr. Rashnonejad.

Full Steam Ahead

- This spirit of innovation, coupled with tremendous intellectual resources and research-centered infrastructure, make Nationwide Children's the optimal place to advance these gene editing-based therapies, regardless of the selected vector or mechanism of choice of the individual researchers.
 - "It is really hard to find an institution that has it all from investigation to manufacturing, clinical teams and a regulatory team, all in one place," says Dr. Naeimi Kararoudi. "People come to us with an idea and we can do it all for you, with proven successes. There are very few places you can do such a thing."
- In addition to facilitating the work of investigators at Nationwide Children's and around the world, Dr. Naeimi Kararoudi has had initial triumphs with several of his own projects as well, including gene therapy to combat multiple myeloma and efforts to make therapies more affordable and accessible. His greatest success to date has been with colleague Dean Lee, MD, PhD, director of the Cellular Therapy and Cancer Immunology Program at Nationwide Children's: an off-the-shelf
 CRISPR/AAV edited natural killer cell therapy for cancer. The technology received "safe-to-proceed" approval from the FDA to treat cancer patients, a first in many aspects.

And the future looks bright. Gene editing experts at Nationwide Children's have open minds, robust funding pipelines, savvy technology commercialization allies and a community of veteran gene therapy experts to question and collaborate with on new ideas. Strong relationships with patient advocacy groups and grassroots funding mechanisms stimulate new project ideas and facilitate connections to the patient community.

As company after company finds its roots in Nationwide Children's intellectual property, the reputation of the Jerry R. Mendell Center for Gene Therapy is only set to grow, providing a rich breeding ground for novel therapies and a brighter future for patients with genetic disorders of all kinds.

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"Dr. Lee and myself, in collaboration with the Institute for Genomic Medicine (Drs. Elaine Mardis and Ben Kelly) have adapted a bioinformatic platform to identify off-targets in CRISPR edited samples. In addition, other orthogonal methods also are used to ensure low off-target effects of CRISPR."

- Meisam Naeimi Kararoudi, DVM, PhD, Director of the CRISPR/Gene Editing Core



Left to right (back row): Yasemin Sezgin, Sriram Vaidyanathan, Dean Lee, Meisam Kararoudi, Zarife Sahenk, Afrooz Rashnonejad (front row): Allison Bradbury, Scott Harper

Varhouse and AVA: Revolutionizing Genomic Data Management and Interpretation

The groundbreaking software system is used for both research and clinical purposes and is transforming how genomic data is organized, interpreted and applied to improve patient care.

hen it comes to working with big data, it doesn't get much bigger than the human genome. Each of our genomes has approximately 6 billion data points, half from one's mother and half from one's father. Compared to the human reference genome, an individual typically harbors 4-5 million genetic variants, a large number of which may be unique to that person Understanding the impact of these variants and their multitude of interactions is crucial to improving our health and management of disease, particularly in pediatric cancer and rare diseases.

Clinicians and researchers use various genome sequencin approaches to identify genetic variants that may be causing a child's cancer or disease. Discerning which variants are potentially causative in each case can be a daunting task.

"Genomics is an example of truly 'big data'," says Dr. Peter White, PhD, chief data sciences officer of the Abigail Wexner Research Institute (AWRI) at Nationwide Children's Hospital and professor of Pediatrics at The Ohio State University College of Medicine.

Upon joining Nationwide Children's 16 years ago, Dr. White started a new genomics initiative that eventually evolved into The Steve and Cindy Rasmussen Institute for Genomic Medicine (IGM). During that time, he and his IGM cofounders began applying genomics to various clinical areas. With the development of new technologies that allowed rapid genome sequencing, the team was creating a vast amount of data that needed to be organized and interpreted.

"When we first started, we were sequencing around 10 patients a year. Now, we're sequencing thousands annually," Dr. White explains. "As the volume grew, we began

t I S	asking ourselves important questions: How do we manage this vast amount of data? How do we organize all these data points for each patient and connect them to their clinical characteristics?"
, 1.	Dr. White and his team of software engineers began developing a system to house and interpret this data, and over the years, they refined it into its current fully functional form, the Variant Analysis Warehouse or Varhouse for short.
ng	Functionality of Varhouse and AVA Their solution, Varhouse, represents the culmination of a decade of research and development. Varhouse is a state-of-the-art genomic data warehouse for large-scale analysis and interpretation of genomic data. It offers cloud-enabled, scalable storage and real-time genomic data analysis.
	"The system is designed to scale with an increasing number of sequenced patients, allowing for long-term data organization and discovery," says Dr. White. "However, Varhouse is not just a data warehouse; it is a tool that empowers researchers and clinicians to harness the full potential of genomic data."
y e	In addition to genomic data warehousing, Varhouse supports data visualization, filtering, variant prioritization, interpretation, clinical report generation and advanced analytics. The analysis is completed by a cutting-edge web-based tool concurrently developed by the Nationwide
ne O	Children's team called Assisted Variant Assessment (AVA). The AVA component has two main functions: annotation and interpretation. Annotation involves identifying genetic variants and their impacts on genes.

Varhouse continuously retrieves the latest genomic annotation data, including publicly available data, and AVA integrates these annotation sources to provide

How It Works



real-time updates, ensuring the latest genomic variant information is always available.

"The field of genomics is rapidly evolving. For example, about 8,000 rare diseases have been described, and every month, an additional 40 to 50 new rare disease genes are discovered," explains Dr. White. "Clinicians can't stay on top of that volume of literature. So, we're using AI technology to bring in all of that information to identify the relevant genetic changes for each patient's condition."

Clinical and Research Applications of Varhouse

Varhouse is integrated into clinical and translational research workflows at Nationwide Children's. At the hospital, it is primarily applied in pediatric cancer, rare disease diagnostics and translational research. It enables the identification of novel genetic variants, guiding targeted treatments and personalized therapeutic strategies and linking patients to relevant clinical trials based on their genetic variants.

Of particular note, Varhouse is being used to store and analyze data from the Molecular Characterization Initiative (MCI), part of the National Cancer Institute (NCI) Childhood Cancer Data Initiative (CCDI) and is a national collaboration between members of the childhood cancer community providing state-of-the-art molecular characterization at the time of diagnosis that helps participants and doctors select the best and most appropriate treatment. However, the data are also made accessible to researchers for future studies.

"Our clinical team uses the Varhouse interface to highlight key variants, such as a TP53 deletion or MYC amplification, to guide treatment decisions," explains Dr. White. "Varhouse is integrated with our clinical reporting software and, after review by one of our clinical directors, automatically de-identifies all data and shares it in real-time with the NCI for global research access."

Integration of Advanced AI in Genomic Data Interpretation

The team at Nationwide Children's has also prioritized the integration of artificial intelligence (AI) and natural language processing algorithms in the interpretation process to prioritize relevant genetic variants. This allows automated data interpretation, streamlining the genomic data analysis and interpretation bottleneck with AI-driven tools, reducing manual workloads, improving diagnostic accuracy and accelerating discoveries.

Natural language processing and large language models are used to read clinical notes and identify relevant thousands of patients. phenotypes linked to genes. Machine learning algorithms "Our software engineers at Nationwide Children's came from many different backgrounds, and they all love the fact that what they're doing here is having such an impact. They are helping find answers for families who have sometimes gone years without a diagnosis, and it is just so rewarding to create something that is helping kids," says Dr. White. "I'm proud to see how our software has evolved, growing from something used initially for research to something now used routinely for patient care."

consider the impact of genetic variants, the match between a patient's clinical characteristics and known disease genes, and inheritance patterns to rank variants. These AI-driven tools are new to Varhouse and are currently being clinically validated. "Using AI, we've gone from looking at hundreds of genetic variants to looking at a handful of genetic variants," says Dr. White. "We can use AI to streamline these processes. A human still makes the final assessment, but AI brings the most likely answers to the top of the list."

The team recently published a proof-of-concept analysis using their machine learning algorithm, CALVaRi. The



"Using AI, we've gone from looking at hundreds" of genetic variants to looking at a handful of genetic variants.

- Peter White, PhD, Chief Data Sciences Officer of the Abigail Wexner Research Institute at Nationwide Children's Hospital

platform identifies likely diagnostic variants for review using clinical characteristics from patient clinical notes. In the study, CAVaLRi identified diagnostic findings in 18 previously non-diagnostic cases non-diagnostic cases.

Impact and Future Directions

Varhouse is routinely used for all patients undergoing diagnostic testing and tumor molecular characterization at Nationwide Children's, with over 4,000 patients sequenced for the MCI so far. The system has been instrumental in helping researchers and clinicians identify the causes of cancers and rare diseases in

Schuetz RJ, Antoniou AA, Lammi GE, Gordon DM, Kuck HC, Chaudhari BP, White P. CAVaLRi: An algorithm for rapid identification of diagnostic germline variation. *Human Mutation*. 2024; 2024(1) 1-15.

Innovative Highchair Design Revolutionizes Pediatric Care: A Collaborative Journey From Concept to Prototype

ighchairs are common in homes with babies and toddlers, as well as in places such as hospitals and restaurants where young children are fed. In hospitals, they are mainly used in pediatric care for infants, toddlers and children undergoing treatment or recovery. Highchairs provide a safe, stable seating option during meals and interactions with family, friends and staff, promoting normalcy and supporting developmental needs.

For children who can sit up and eat, highchairs help them eat safely in an upright position, reducing the risk of aspiration. They also facilitate socialization, allowing children to interact with family during visits or participate in therapeutic activities. However, the design and adaptability of highchairs for all children are somewhat limited.

In 2021, Shelley Coleman Casto, MS, OTR/L and Melanie Stevens, MS/CCC-SLP, BCS-S, both occupational therapists, developed an innovative concept for a new highchair and began working with Kyle Murrah, senior licensing associate in the Office of Technology Commercialization at Nationwide Children's Hospital. This marked the beginning of a collaborative journey that would involve multiple stakeholders and lead to the creation of a novel highchair designed to benefit children's health.

Michelle Wollenberg and Alisa Pinciotti, who are involved in purchasing and construction at Nationwide Children's, played pivotal roles throughout the project. They suggested reaching out to Columbus College of Art & Design (CCAD), a leader in art and design education located in downtown Columbus, for assistance with the design. CCAD was enthusiastic about the project and saw it as an excellent opportunity for their students to engage in a real-world design challenge.

"Health care design is an impactful space that we love connecting our students with through partnered projects," said Nicole Monahan, associate vice president for Creative Careers & Collaboration at CCAD. "To know that CCAD students and faculty could design a real highchair that would help babies and children was especially meaningful to us all."

Thus, an agreement was executed between CCAD and Nationwide Children's.

The project officially kicked off in the spring semester of 2023. Students from CCAD began by shadowing Coleman Casto and Stevens to gather research on the highchairs currently in use. This hands-on approach allowed the students to understand the practical needs and challenges faced by occupational therapists and their young patients.

Throughout the semester, various collaborative work sessions were held on the CCAD campus to identify key design criteria and user experience considerations. Co-design sessions were conducted to inspire innovative solutions for the highchair. These collaborative efforts culminated in a presentation at the end of the semester, where students shared their findings, including essential design needs, materials and features. Broad proposals for the design elements were laid out, setting the stage for the next project phase.

The spring semester of 2024 marked the beginning of the actual design of the highchair. The kickoff event featured a patent presentation by Kyle Murrah and Joseph Mills, PhD, licensing associate in the OTC, highlighting the importance of protecting the innovative aspects of the design. These include innovative design features such as low muscle tone support, a chair sliding track and nesting capabilities.





Steele Clevenger, senior in Product Design at Columbus College of Art & Design. Photo by Sarah Pfeifer.

Throughout the semester, clinicians and Nationwide Children's personnel provided valuable feedback during presentations held at Nationwide Children's. This iterative process ensured that the final design met the practical needs of its users.

The semester concluded with the presentation of a final design and a prototype.

"The clinicians and staff at Nationwide Children's were amazing collaborators and provided our students with a fantastic career-building experience," says Monahan. "It was a joy to celebrate the final design with Melanie and Shelley, who had dreamed of it for so long."

As the team moves into the final stages of filing a utility patent on key elements of the highchair, the contributions of Shelley, Melanie, and the CCAD team remain central to the project's success.

Leveraging Technology and Partnerships to Transform Pediatric Orthopedic Care

t Nationwide Children's Hospital, the Department of Orthopaedics drives pediatric health care innovation through collaborations that bridge clinical expertise and technological advancement. Specializing in areas like spinal deformities, trauma care and sports medicine, the team addresses unique developmental needs to create solutions tailored for children. Central to this effort is the Center for Orthopedic Innovation, which works alongside the Office of Technology Commercialization (OTC) to transform groundbreaking ideas into practical applications.

"Reimagining possibilities in pediatric orthopedic care is at the heart of what we do," says Allen Kadado, MD, director of the Center for Orthopedic Innovation. Through an integrated approach combining clinical care, research and commercialization, the Orthopedics department is advancing a robust pipeline of innovations designed to improve care for young patients.



An interview with Allen A. Kadado, MD, director of the Nationwide Children's Hospital Center for Orthopedic Innovation, Director of the Nationwide Children's Pediatric Orthopedic Residency Program

How does the Department of Orthopaedics at Nationwide Children's Hospital push the boundaries in pediatric health care?

The Department of Orthopaedics addresses children's unique needs with customized devices and procedures. Known for its expertise in spinal deformities, trauma and sports medicine, the department partners with OTC and other innovators to eliminate barriers to pediatric care, such as regulatory and economic challenges.

Dr. Kadado says, "Our team constantly reimagines what's possible for children needing orthopedic care."

OTC's support has been instrumental in helping the department overcome regulatory and financial hurdles that have historically kept pediatric device innovation 5-10 years behind adult devices. With OTC's expertise, the team is confident in navigating complex pathways

that protect intellectual property and expedite device development for children.

What are some recent innovations in pediatric orthopedic care at Nationwide Children's?

The department has developed several impactful innovations, including:

• 3D Scoliosis Biomechanical Model: This high-fidelity model enables enhanced training and surgical precision, offering physicians realistic practice scenarios for spinal correction. As a future standard for scoliosis simulation, it holds potential for fusion-less treatment options, a promising direction in pediatric scoliosis care.

• Brace Compliance Program: By combining wearable sensors with cloud analytics, this program monitors patient adherence to prescribed brace wear, sending

timely alerts to caregivers if a patient deviates from treatment. The system supports better long-term outcomes by ensuring consistent treatment adherence.

• Ligamentum Teres Reconstruction for Hip Dysplasia:

Using minimally invasive techniques, the team developed child-friendly solutions for hip dysplasia. This treatment approach improves children's mobility and quality of life, especially for complex hip issues.

• Halo Gravity Traction Program for Home Use:

Designed for medically complex young patients, this program allows for monitored traction therapy at home, enhancing patient and family experience while offering critical spinal treatment. The real-time monitoring capabilities provide caregivers peace of mind and ensure safe, effective use.

How does OTC help the Department of Orthopaedics address barriers in pediatric device development?

The OTC plays a crucial role in overcoming challenges unique to pediatric device innovation, which include high development costs, extensive regulatory requirements, and a smaller market. These factors have traditionally delayed device innovation for children, often requiring clinicians to repurpose adult devices for pediatric use. The OTC provides a structured approach to navigating these regulatory and economic barriers, assisting in securing funding and guiding intellectual property strategies that support device development specifically for pediatric use.

"Protecting intellectual property can be tricky," Dr. Kadado says, "but with OTC's expertise, we confidently navigate these complexities and bring innovations to patients faster."

The OTC's support has been essential for projects like the 3D scoliosis model, helping the team efficiently move through regulatory pathways and protect innovative designs.

What is the significance of OTC's partnership with the Orthopedics team?

Monthly meetings between OTC and the Orthopedics How is artificial intelligence (AI) integrated into the team are essential to Nationwide Children's innovation department's innovations? pipeline, allowing for fast-tracked movement from concept to patent submission, IP strategy and licensing. AI is integral to improving outcomes within the With OTC's support, the team has already submitted Department of Orthopaedics, particularly in tracking



Cheyenne Wolfe, 9, receiving treatment for spinal deformity with long-term halo traction.

ten Invention Disclosure Forms and two U.S. provisional patent applications. In these sessions, OTC also provides critical funding guidance, which prioritizes essential projects such as the 3D scoliosis model and the halo gravity traction device.

adherence, analyzing device wear and tailoring patient support. Real-time compliance tracking provides timely alerts, allowing for rapid adjustments that help optimize outcomes. Additionally, partnerships with industry leaders in AI allow the department to incorporate advanced AI applications into preoperative planning and predictive modeling. These AI tools not only improve surgical precision and patient safety but also enhance clinicians' ability to tailor procedures to individual needs, positioning the Department of Orthopaedics as a leader in AI-driven health care solutions.

How does the Department of Orthopaedics prepare future leaders in pediatric orthopedic innovation?

The Pediatric Orthopedic Clinical Innovation Fellowship provides a yearlong training program, giving participants hands-on exposure to research, IP management, prototyping and commercialization. The fellowship equips future leaders with the knowledge needed to handle every stage of device development.

"We're training the next generation of orthopedic leaders who are skilled not only in clinical care but also in navigating the regulatory and business complexities of pediatric device innovation," says Dr. Kadado.

This program is critical in creating a pipeline of clinicians and researchers prepared to lead advancements in pediatric orthopedics.

How does Nationwide Children's collaborate with the Midwest Pediatric Device Consortium (MPDC)?

The MPDC, supported by Nationwide Children's and The Ohio State University, expands the reach of the Orthopedics department's innovations by connecting it with a larger network of universities, health care systems and industry partners. MPDC helps facilitate regulatory support, funding and mentorship, allowing clinicians and researchers to bring devices to market more quickly. This partnership reflects a commitment to making pediatric-specific devices accessible nationwide and highlights the importance of industry collaboration in transforming pediatric care.

What are the department's top priorities moving forward?

The department is committed to creating user-friendly, less invasive devices specifically designed for pediatric patients. Collaborations with OTC and MPDC are crucial for realizing this vision by providing the resources necessary for prototyping, regulatory guidance and expanding market access. The department is also exploring advancements in AI-driven analytics, imaging modalities and fusion-less technology.

Dr. Kadado says, "We're working toward a future where pediatric patients everywhere have access to the latest advancements in orthopedic care, tailored specifically to their needs."

CONCLUSION

Through ongoing initiatives and partnerships with OTC, MPDC and AI industry leaders, Nationwide Children's Orthopedics department is at the forefront of pediatric innovation, offering young patients the most advanced and effective orthopedic care available. Dr. Kadado and his team exemplify a dedication to a future where pediatric care meets the specific needs of every child, enhancing both immediate and long-term quality of life.





ApollOS



eSuction

MEDICAL DEVICES ON THE MARKET



ApollOS



Comfort Collar

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.

medical devices and digital health."

- Margaret Barkett, PhD, Interim Director of Office of Technology Commercialization and Director of Licensing









CLARAMETYX



HYPERPATH

SOLUTIONS

















"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,





RxGames





🔆 small**Talk**

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 1,800 faculty work in over 100 subspecialties and 15 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 2023-2024 Annual Report.



RESEARCH INSTITUTES AND 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** ٠
- 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
- Jerry R. Mendell Center for Gene Therapy
- Center for Injury Research and Policy

- Center for Microbe and Immunity Research
- Center for Perinatal Research
- Center for Regenerative Medicine
- Center for Suicide Prevention and Research
- 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





	2022	2023	2024
Principal Investigators*	249	264	268
Research Fellows	78	93	110
Graduate Students	61	68	76
Employees	1613	1815	1956
Publications	1740	1820	1867

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

2024 EXTERNAL AWARDS



2024 \$152.0

RESEARCH BY THE NUMBERS

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 750,000 square feet across campus.

MAIN CAMPUS HIGHLIGHTS

- 1,563,577 square feet of inpatient space.
- 681,415 square feet of outpatient space.
- 756,916 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





suspension for intravenous infusion

For patients with spinal muscular atrophy (SMA)



Technology commercialization continues to flourish at Nationwide Children's, which allows more opportunities to reinvest back into research and continue to strive for best outcomes for children in Columbus and around the world.

2024 AUTM Better World Project Finalist

Columbus Business First recognized Nationwide Children's Hospital for the highest income from technology licensing of any Ohio research institution.

FDA-APPROVED GENE THERAPIES

Elevidys delandistrogene moxeparvovec-rokl

suspension for intravenous infusion

For patients with Duchenne muscular dystrophy (DMD)

2024 AWARDS



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