2020 Technology & Innovation Development Office
ANNUAL REPORT

Boston Children’s Hospital
Where the world comes for answers
2020 WAS A YEAR TO REMEMBER.

COVID-19 sent the TIDO team home to work remotely, the Children's research labs shut down and the hospital's clinical enterprise teetered while we all got our bearings. We learned how to wear masks and work remotely to continue the mission of translating research while preventing COVID. In the summer, the wheels started turning again: the labs opened and the biotech companies came roaring back, leading to a tremendous year in the end.

Some highlights this year were the creation of new and meaningful support for translational research at Children's. The hospital launched our new internal incubator, D3A, focused on bringing drugs, devices and diagnostic discoveries closer to the market through de-risking high-potential projects. Children's entered into a major strategic alliance with Deerfield, bringing Deerfield's funding (up to $65M) and drug development expertise to Children's investigators. We launched an alliance with Beam Therapeutics, focused on next-generation gene therapy and single base pair gene-editing. A number of additional translational alliances are also in the works. Each of these alliances brings funding and commercial expertise to Children's investigators and technologies, strengthening our ability to translate our discoveries into lifesaving treatments.

Before closing, I want to add some personal thoughts on COVID, vaccines and the value of basic biological research. At TIDO we have a team of talented individuals who are committed to translating basic laboratory research into products and treatments which improve patients' lives. We believe in and live this mission every day; however, this year we saw that mission truly realized. The novel COVID vaccines are based upon discoveries made in fundamental academic research; their speedy translation to human use came from many years of partnership with industry. The substance of the first approved vaccines, from Modera (founded on seminal research from Dr. Derrick Rossi, here at Children's) and Pfizer and BioNT are based on insights into mRNA, one of the fundamental building blocks of life. Many, many years of academic research unlocked the insight that RNA has a larger role in biology than simply being a copy machine for DNA. Years of research on RNA delivery, both in academia and industry, led to the development of methods for delivering RNA to people for therapeutic purposes. Those years of basic academic and industrial research on RNA and RNA delivery laid the foundation for the incredibly rapid response to COVID-19. When I got my Pfizer vaccine at Children's, I was so moved to see those many years of dedicated research come to fruition. Waiting my fifteen minutes in the Folkman auditorium under Judah Folkman's benevolent gaze made me so grateful to be part of this sacred mission to bring scientific discoveries from the lab to the bedside to change the world for the better.

Irene Abrams
Vice President, Technology Development and New Ventures
Technology & Innovation Development Office
TIDO in

FY20

- **RESEARCH EXPENDITURES**: $423,217,000
- **NEW INDUSTRY-SPONSORED RESEARCH FUNDING**: $16,314,436
- **RESEARCH AGREEMENTS**: 63
- **LICENSING AGREEMENTS**: 52
- **GROSS LICENSING REVENUE**: $21,071,188

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*On the cover*

Platelets being born: the cytoskeleton of a megakaryocyte forming platelets in vitro.

Isabelle Becker of the Italiano Lab
Vascular Biology Program
Agreements

LICENSE, OPTION, & RESEARCH AGREEMENTS 115
CONFIDENTIALITY 162
RECEIPT OF EQUITY 4
MATERIAL TRANSFER 333
INTER-INSTITUTIONAL INVENTION ADMINISTRATION 12
CONTRACT RESEARCH ORGANIZATIONS 46
AMENDMENTS 6
OTHER 45

Revenue

REVENUE FROM FY20 LICENSES AND OPTIONS $666,462
GROSS REVENUE $21,701,188

Start-ups

Autus
Quantivly
Cellvie
Dock Health

Impact

ACADEMIC PARTNERSHIPS 203
INDUSTRY PARTNERS 257
STARTUPS CREATED 4
CORPORATE SPONSORED RESEARCH & COLLABORATIONS 63
Orchard Therapeutics has signed agreements with Boston Children’s Hospital to develop hematopoietic stem cell gene therapy approaches developed by Alessandra Biffi, MD (Gene Therapy Program) for indications in neurodegenerative diseases, including the treatment of amyotrophic lateral sclerosis (ALS) and GRN-frontotemporal dementia (GRN-FTD). Dr. Biffi’s group has developed a gene therapy strategy based on the transplantation of engineered hematopoietic stem and progenitor cells (HSPCs) aimed at generative microglia progeny for the regulated and long-lasting expression of molecules whose expression has been implicated in neuroprotection and in favorably modulating neuroinflammation. The pre-clinical program in GRN-FTD seeks to introduce a working copy of the GRN gene into HSCs, which can differentiate into microglia and secrete progranulin in the central nervous system, potentially correcting the underlying cause of the disease. The ability of HSC gene therapy to restore healthy microglia function supports the use of this technology for the development of treatments for a variety of diseases with central nervous system involvement.

Small interfering RNAs (siRNAs) are a class of double-stranded short non-coding RNA molecules that are able to silence the expression of genes with complementary sequences. As such, they have immense potential in gene therapy applications to enable the silencing of disease-causing genes. Technology developed in the laboratory of Judy Lieberman, PhD (Cellular and Molecular Medicine) makes it possible to produce siRNAs in bacteria such as E.coli–so-called prokaryotic siRNAs (pro-siRNAs)–that could be engineered to silence any mammalian gene with minimal off-target effects. The ability to make potent siRNAs in a microorganism would enable large-scale and cost-effective development of siRNA products for in vivo studies as well as therapeutic applications. Xiaomo, a biotechnology company in Hong Kong with an innovative platform to develop siRNA, has exclusively licensed this technology to produce and bring to market potent siRNAs for agricultural and gene therapy applications.
IDEAYA, a San Francisco-based pharmaceutical company that specializes in developing therapeutics and biomarkers for the treatment of cancer, is sponsoring research in the lab of Joyce Bischoff, PhD (Surgery) to evaluate the role of protein kinase C (PKC) in Sturge Weber syndrome (SWS), a rare neurocutaneous disorder characterized by capillary malformations and with symptoms such as facial birthmarks, seizures, and glaucoma. There are no current treatments for SWS, which is believed to be associated with mutations in GNAQ in the skin and brain tissue which enhances signaling in the PKC pathway. The research will evaluate IDE196, a selective PKC inhibitor through in vitro experiments to determine whether inhibition of PKC can restore normal function to GNAQ-mutated endothelial cells. The research will also include in vivo experiments in murine models to assess whether pharmacological inhibition of PKC can regulate enlarged blood vessels that are characteristic of SWS.

FY20 Highlights

New Technology

Adjuvant Modifiers of the Human Immune Response to Enhance Vaccines and Treat Cancer

Supported by the National Institutes of Health and BCH’s TIDO, Ofer Levy, MD, PhD and David J. Dowling, PhD of the Precision Vaccine Program have discovered multiple classes of small molecule adjuvants to be used as enhancers and/ or modifiers of immune response that enhance vaccine responses. The approach uses small molecules such as imidazopyrimidines to induce a robust activation of human leukocytes in vitro and to act as adjuvants in vivo. Using such adjuvants can enhance, prolong, and modulate immune responses to vaccinal antigens to maximize protective immunity, reduce the number of doses required for protection, and potentially enable effective immunization in vulnerable populations (e.g., the very young and the elderly). Vaccine adjuvants also hold great potential as cancer immunotherapeutics as a growing body of literature based on animal studies and human clinical studies suggests the potential of small molecule immune response activators to enhance antitumor responses.
Sickle cell disease and β-thalassemia are a group of blood disorders characterized by abnormal adult hemoglobin synthesis which prevents hemoglobin from effectively carrying oxygen through the bloodstream. Approximately 5% of the world’s population are carriers of an abnormal gene critical for hemoglobin synthesis that gives rise to sickle-cell disease or β-thalassemia. Blood transfusions are a standard treatment for these disorders and though this procedure may reduce symptoms, a bone marrow transplant, which is risky and requires finding a matched donor, is the only current cure. However, a discovery made by researcher Stuart Orkin, MD (Cancer and Blood Disorders Center) has led to a promising potential treatment. Orkin’s lab, including Daniel Bauer, MD, PhD (Cancer and Blood Disorders Center), a research fellow at the time, discovered that suppressing the gene BCL11A through gene editing technologies such as CRISPR could restart fetal hemoglobin production. A patient can then receive chemotherapy to wipe out the diseased cells, followed by a transfusion of the altered stem cells. With the fetal gene active, missing hemoglobin is then restored in thalassemia. In sickle cell disease, it can replace some of the flawed adult hemoglobin and block any remaining from forming sticky polymers. The research, licensed to CRISPR and Vertex Pharmaceuticals, has led to the first U.S. human clinical trials of such a gene-editing approach for sickle cell disease. The treatment gained Fast Track Designation from the U.S. Food and Drug Administration, and in December 2020, CRISPER and Vertex presented new clinical trial data showing consistent and sustained health improvements in patients treated with the therapy, named CTX001.

**Milestones**

**CRISPR gene editing for Sickle Cell Disease and β-thalassemia**

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**Affinivax Announces Phase 1 Clinical Data**

Affinivax, a clinical-stage biotechnology company developing new approaches in vaccine technology, initiated Phase 1/2 clinical studies of ASP3772, a novel vaccine targeting pneumococcal disease, in February 2019. Phase 1 of the trials has now been completed and the vaccine was shown to be safe and well-tolerated in adults 18 to 64. The vaccine was developed through a partnership with Astellas using Affinivax’s proprietary vaccine platform, called the Multiple Antigen Presenting Systems (MAPS). MAPS was developed at Boston Children’s Hospital by three researchers who are all scientific founders of Affinivax: Richard Malley, MD, Fan Zhang, PhD, and Yingjie Lu, PhD (Division of Infectious Diseases). The program advanced from the labs of Boston Children’s Hospital to clinical testing in less than five years.

**Vigeo Therapeutics Doses First Patients in Phase 1b/2 Clinical Trials**

Vigeo Therapeutics, co-founded by Randolph Watnick, PhD (Surgery), a clinical-stage biopharmaceutical company committed to developing novel therapeutics to effectively treat multiple types of cancer, has dosed the first patients in its Phase 1b/2 clinical trial evaluating VT1021, a small peptide that reprograms the tumor immune microenvironment (TIME) by targeting CD36 and CD47 via Tsp-1 Induction to stop tumor growth. The Phase 1b/2 study will enroll approximately 75 patients with 15 patients in each of five groups: ovarian cancer, pancreatic cancer, triple-negative breast cancer, glioblastoma, and a tissue agnostic group of patients with high CD36 expressing tumors.
Boston Children’s Hospital and Beam Therapeutics, a Cambridge-based biotechnology company pioneering next-generation gene therapy, formed a strategic alliance to facilitate the development of disease-specific therapies using Beam’s base editing technology. As part of the three-year agreement, Beam will sponsor multiple research programs at Boston Children’s Hospital including programs in sickle cell disease and pediatric leukemias as well as the exploration of new disease areas. Boston Children’s Hospital will also serve as a clinical site in the future to advance bench-to-bedside translation of Beam’s pipeline.

Deerfield Management Company, a healthcare investment firm, announced a major research collaboration to advance promising therapeutics that will address unsolved medical needs and find cures for disease. As part of the collaboration, Deerfield will provide up to $65 million in funding for a new research collaboration with Boston Children’s Hospital focused on drug discovery and development.

Boston Children’s physicians and scientists will have the opportunity to submit proposals for review to a committee of scientific leadership from both the Hospital and Deerfield. To manage this collaboration, Deerfield has created a new entity, Blackfan Circle Innovations, named in honor of Kenneth Blackfan, MD, an early leader in childhood blood disorders and pediatric diseases and a distinguished late faculty member from Boston Children’s Hospital.

Astellas, a research-oriented global pharmaceutical company with a strong oncology pipeline, has entered into an alliance with Boston Children’s Hospital and is sponsoring two research projects concerning RNA homeostasis pathways relating to cancers. One such project is conducted by Suneet Agarwal, MD, PhD (Hematology/Oncology); the other is conducted by Richard Gregory, PhD (Stem Cell Program) and Alejandro Gutierrez, MD, FAAP (Hematology/Oncology). The researchers have identified new pathways and targets in the field of RNA homeostasis which could be targeted for the development of anti-cancer drugs. These sponsored research projects could additionally lead to novel avenues for treating cancers.
FY20 Highlights

Bridging the translational gap

The Technology Development Fund
The Technology Development Fund (TDF), established in 2009, is Boston Children’s Hospital’s internal mechanism for translating high-impact new technologies into the independently validated, later-stage opportunities sought by industry partners and investors. Technologies funded by TDF range from therapeutics and devices to diagnostics and vaccines in both pediatric and adult indications.

The Technology Development Fund provides:
- Mentoring and coaching through an advisory board of industry leaders in product development to identify and reach key milestones toward product development
- Funds to execute the scope of work agreed upon with the mentors
- Technical support and expertise through a network of service providers and collaborators
- Active project management to maintain focus on development goals

The 2020 Awardees
Selected from 23 applications

Targeting of the YAP-TEAD protein-protein interaction as a novel therapeutic approach in cancer
Fernando Camargo, PhD, Stem Cell
Sophia Shalhout, PhD, Hematology/Oncology

Development and Evaluation of a Micro-particle with Extended Release
Juan Ibla, MD, Anesthesiology, Critical Care and Pain Medicine
Daniel Kohane, MD, PhD, Anesthesiology, Critical Care and Pain Medicine

Targeted delivery of therapeutic antibodies into motor neurons for treating botulism
Min Dong, PhD, Urology

Transcatheter Mitral Chordal Replacement System
Pierre Dupont, PhD, Cardiac Surgery

Safe Sensory-selective Local Anesthetics
Daniel Kohane, MD, PhD, Anesthesiology, Critical Care and Pain Medicine
FY20 Highlights

Bridging the translational gap

Drug, Device, and Diagnostic Accelerator

The Drug, Device, and Diagnostic Accelerator (D3A) launched at Boston Children’s Hospital in 2020. D3A is an internal accelerator focused on the development of high-potential drug, device, and diagnostic inventions that may lead to advanced commercialization and significant patient impact. Building on the successful efforts of the Technology Development Fund (TDF) and Translational Research Program (TRP), D3A works with BCH physicians and scientists to identify innovations that will benefit from expert advice, additional investment of capital, program management, and external technical resources to fast-track ideas into full-scale development.

Goals

- **Enhance translation of science** into novel and innovative new therapies, devices and diagnostics that meet a significant, unmet medical need for children while doing so in a capital and time efficient manner
- **Improve commercialization** and expedited clinical development awareness and skill among faculty
- **Increase value** of BCH scientific discoveries and expedite the translation of these into our clinical mission and/or increase ROI of research investments to BCH
- **Unite similar existing programs** into one comprehensive new structure that will simplify and efficiently manage high-value discovery programs

D3A Team

William Clarke, MD
Faculty Director

Mei-Mei Huang, PhD, MBA
Program Manager

For more information about D3A, please email D3A@childrens.harvard.edu or contact Bill Clarke, MD, Faculty Director, at William.Clarke@childrens.harvard.edu.
Issued U.S. Patents

10,736,906
Method to enhance tissue regeneration
Zon, Leonard

10,786,232
10,786,238
Methods and procedures for ligament repair
Murray, Martha

10,736,626
Tissue clip
Del Nido, Pedro

10,670,600
Saposin-A derived peptides and uses thereof
Watnick, Randolph

10,532,132
Implantable drug delivery device and methods
Cima, Michael

10,765,757
Mucosal delivery of therapeutic molecules, proteins, or particles coupled to ceramide lipids
Lencer, Wayne

10,570,392
Modulation of BCL11A for treatment of hemoglobinopathies
Orkin, Stuart

10,463,729
10,653,770
Biochemically stabilized HIV-1 Envelope vaccine
Harrison, Stephen

10,577,554
Gas-filled stabilized particles and methods of use
Kheir, John

10,457,733
Agents that modulate immune cell activation and methods of use thereof
Umetsu, Dale

10,508,276
Methods and compositions for the production of siRNAs
Lieberman, Judy

10,745,737
Methods and reagents for glycoproteomics
Lee, Richard

10,456,445
Methods and compositions for immunomodulation
Briscoe, David

10,588,695
Catheter device for transmitting and reflecting light
Del Nido, Pedro

10,667,627
Devices and methods for supporting and containing premature babies and small-for-age infants
Degrazia, Michele

10,472,419
Antibody molecules to TIM-3 and uses thereof
Umetsu, Dale

10,646,541
Cyclic prosaposin peptides and uses thereof
Watnick, Randolph

10,624,929
Methods and compositions relating to exosomes
Kourembanas, Stella

10,669,528
Methods and compositions relating to hematopoietic stem cell expansion, enrichment, and maintenance
Rossi, Derrick

10,457,899
PD-L1 expressing hematopoietic stem cells and uses
Fiorina, Paolo
10,569,075
Apparatuses for cleaning catheter ports
Kheir, John

10,640,820
Methods relating to the detection of recurrent and non-specific double-strand breaks in the genome
Alt, Frederick

10,765,664
Treatment of infectious diseases
Goldfeld, Anne

10,668,039
Methods for treatment of adenoid cystic carcinoma
Zon, Leonard

10,456,102
Automated apparatus to improve image quality in X-ray and associated method of use
MacDougall, Robert

10,570,207
Compositions and methods for non-myeloablative conditioning
Rossi, Derrick

D846,755
High throughput screen of small molecules
Wong, Wesley

10,650,228
Devices and methods for analyzing animal behavior
Roberson, David

10,730,983
Biocompatible coatings and hydrogels for reducing foreign body response and fibrosis
Doloff, Joshua

10,470,799
Origami robots, systems, and methods of treatment
Rus, Daniela

10,478,290
Expandable stent valve
Del Nido, Pedro
Technology & Innovation Development Office

The Technology & Innovation Development Office (TIDO) maximizes the impact of Boston Children’s Hospital innovations on patient health while enhancing the research endeavor. The TIDO team is comprised of specialists in licensing, patenting, business development, marketing, startup formation and legal matters. We work closely with Boston Children’s investigators and clinicians to develop innovations, protect and license intellectual property, and enable collaborations with companies at all stages of development.

The FY20 TIDO Team

DIRECTORS
Irene Abrams Vice President, Technology, Development, and New Ventures
Catherine Ives, PhD Senior Director, Business Development and Licensing
Tamar Alon, PhD, MBA Director of Business Development & Strategic Alliances
Mikael Bristow, MBA Director of Administration and Operations
Gregory Pivarnik, JD Assistant Director of Contracts

TEAM MEMBERS
Uyi Agho, JD Senior Contracts Specialist
Jennifer Chou, PhD Licensing Specialist
James Degar MTA Specialist
Khadija Elabid Associate Director, Technology Development Fund
Inez Falcon-Haus, PhD Licensing Specialist
Nazita Gamini, JD Licensing Manager
Mei-Mei Huang, MBA Entrepreneur in Residence
Monica Jang Licensing Manager
Rebecca Jones Marketing and Communications Specialist
Sharon Jordan-Prioleau, MBA Business Manager
Alice Li, JD Contracts Specialist
Ayan Pal, PhD Licensing Manager
Lisa Pight Financial Assistant
Ingrid Robison Executive Assistant
Shreya Sawant Strategic Alliances and Communications Specialist
James Simmons, PhD Licensing Manager
Stanley Tabi, JD Patent Coordinator
TIDO Fellows Program

This year TIDO was proud to welcome several BCH post-doc fellows onto our team as part of our new TIDO Fellows Program. Within the program, the fellows work part-time to assist our licensing managers in their assessments of the technical and market potential of BCH inventions. The fellows work alongside the licensing managers to design marketing materials to bring innovative BCH science to the outside world while learning about the field of technology transfer and intellectual property management, gaining first-hand experience in market research, competitive landscape, and prior-art research.

FY20 TIDO FELLOWS

Dijana Vitko, PhD
Since 2017, Dijana has been a postdoctoral fellow in the Department of Urology at Boston Children’s Hospital. In the lab, she focuses on translational research and clinical mass spectrometry for the discovery and validation of disease biomarkers that have diagnostic and prognostic potential. Dijana holds an MS in Molecular Biotechnology from the University of Zagreb, Croatia, and a secondary MS in Bioindustrial Techniques from the University of Orléans, France. She completed her PhD at The CeMM Research Center for Molecular Medicine, where she specialized in mass spectrometry-based proteomics and earned her doctoral degree in Immunology from the Medical University of Vienna, Austria.

Davood Karimi, PhD
Davood obtained his PhD in Electrical and Computer Engineering from the University of British Columbia (UBC) in Canada. His dissertation was focused on image reconstruction and enhancement for cone-beam computed tomography. After completing his PhD, he worked as a postdoctoral research fellow at UCLA and UBC, focusing on projects centered on developing machine learning-based methods for medical image segmentation, cancer detection, and grading in digital histopathology. His current work at IMAGINE involves the development of new algorithms and techniques for motion-robust fetal imaging and the analysis of early brain development.

Ha-Thi Hoang, MD, PhD
Thi is a research fellow in Christopher A. Walsh’s lab in the Division of Genetics & Genomics where he develops novel single-cell sequencing technologies to study neuropsychiatric diseases. He was a fellow at The Engine, a venture capital company built by MIT, and is consultant for life science startups in the US and Europe. Before moving to Boston, Thi started a biotech startup in London, UK, and a non-profit science hackspace in Austria. Thi obtained his PhD in Molecular Biology & Neuroscience from the University of Cambridge, UK, and his MD at the Free University of Berlin, Germany. He was a research fellow in Pharmacology & Neuroscience at Yale University.

Adam Fiseha Kebede, PhD
Adam joined TIDO as a fellow in September 2020 to support the licensing team in evaluating BCH-born technologies, perform prior art searches, and analyze commercialization potential while actively learning about how technology transfer works at the intersection of science and business. Adam is a postdoctoral research fellow in the Shi laboratory, currently studying potential therapeutic vulnerabilities of a pediatric brain cancer known as DIPG through biochemical and genomics approaches. Originally from Ethiopia, Adam moved to Germany for his undergraduate studies where he also started graduate school at the Max Planck Institute in Freiburg and earned his PhD in 2016.

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About Boston Children's Hospital

Boston Children's Hospital is ranked the #1 children's hospital in the nation by U.S. News & World Report and is the primary pediatric teaching affiliate of Harvard Medical School. Home to the world's largest research enterprise based at a pediatric medical center, its discoveries have benefited both children and adults since 1869. Today, 3,000 researchers and scientific staff, including 9 members of the National Academy of Sciences, 22 members of the National Academy of Medicine, and 12 Howard Hughes Medical Investigators comprise Boston Children’s research community. Founded as a 20-bed hospital for children, Boston Children's is now a 415-bed comprehensive center for pediatric and adolescent health care. For more, visit our Discoveries blog and follow us on social media @BostonChildrens, @BCH_Innovation, Facebook and YouTube.
Mailing Address
Technology and Innovation Development Office
300 Longwood Avenue, MS 3183
Boston, MA 02115

Office Location
401 Park, 7 East

617-919-3019 | fax 617-919-3031
TIDO@childrens.harvard.edu
tido.childrenshospital.org