Annual Report | 2024

SOUTHWEST-MIDWEST NATIONAL PEDIATRIC DEVICE INNOVATION CONSORTIUM

Supporting the Pediatric Innovators of Today

Texas Children's Hospital | Baylor College of Medicine | Texas A&M | Rice | UH | Minnesota | PDIC The Pediatric Device Innovation Consortium thepdic.org

SWPDC.org | SouthwestPDC@bcm.edu | 832-822-3160

Our Team

Chester Koh
Founder & Principal Investigator
Texas Children's / Baylor College of Medicine

R. Brandon Hunter
Associate Director
Texas Children's / Baylor College of Medicine

Christine Luk
Portfolio Manager
Proxima CRO

Balakrishna Haridas
Deputy Director; Principal Investigator
Texas A&M University

Gwenyth Fischer
Pediatric Device Innovation Consortia Director; Principal Investigator
University of Minnesota

Matthew Wettergreen
Principal Investigator
Rice University

Richard Wilson
Principal Investigator
University of Houston

Achu Byju
Sr. Research Engineer/Project Manager
Texas A&M University

Jhalak Mehta
CobiCure Fellow
Texas Children's / Baylor College of Medicine

Soniya Naik
Intern
Texas A&M University

Steering Committee

Ellie Reynolds, Proxima CRO - ***Regulatory***
Isabella Schmitt, HeartSciences Inc - ***Regulatory***
Jeff Albertson, Quest Medical - ***Commercialization***
Justin Meade, TCH Innovation Hub - ***Hospital Administration***
Robert Kroslowitz, Berlin Heart, Inc. - ***Pediatric Device CEO***

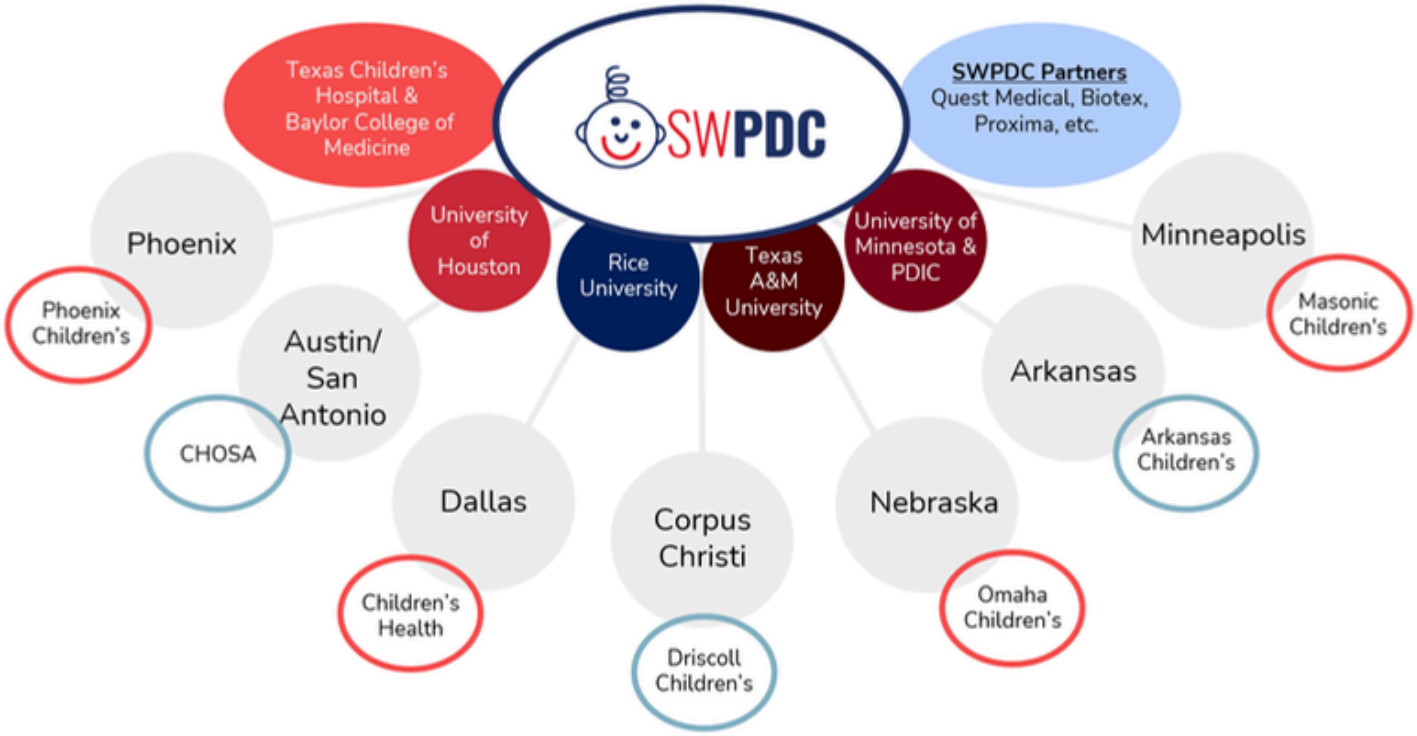
Advisory Committee

Xina Quan, Pyrames - ***Commercialization***
Alan Cooper, Cooper Consulting - ***Engineering & Manufacturing***
Ashok Gowda, Biotex Medical - ***Engineering & Manufacturing***
John Reale, TMC Venture Fund - ***Investment***
Joe Cunningham, Sante Ventures - ***Investment***
Gordan Schatz , Schatz Reimbursement Strategies - ***Reimbursement***
Michael Ritche, Phoenix Children's Hospital - ***Clinical***
Susan Alpert, Susan Alpert Consulting - ***Regulatory***
Emily Reiser, TMC Innovation - ***Accelerator/Hub***
Ann Tanabe, BioHouston - ***Accelerator/Hub***
Michael Dilling, BCM Licensing Group - ***Intellectual Property***

SWPDC

Partners

The SWPDC's collaborative efforts span various regions including Houston, Dallas, Phoenix, and more, focusing on advancements in pediatric care and medical education.



Baylor College of Medicine

Texas Children's Hospital

ENGINEERING

RICE

Cullen College of Engineering
UNIVERSITY OF HOUSTON

PROXIMA CLINICAL RESEARCH

Ignite
Women Shaping the Future of Healthcare

TMC INNOVATION

Johnson & Johnson
INNOVATION JLABS

SwRI
SOUTHWEST RESEARCH INSTITUTE

UT DALLAS

CHRISTUS CHILDREN'S

Driscoll Children's Hospital

children'shealth

UTSouthwestern Medical Center

QUEST Medical, Inc.

Phoenix Children's

Arkansas Children's Hospital

HealthTech ARKANSAS

Child Health Research Institute

University of Nebraska Medical Center

Children's NEBRASKA

HEALTH
University of Minnesota
Masonic Children's Hospital

PDIC
The Pediatric Device Innovation Consortium
thepdic.org

Our Mission:

To enhance the development, production, and distribution of pediatric medical devices nationwide

Come and Join Us

ABOUT US

SWPDC is one of five U.S. Food and Drug Administration (FDA) P50 grant-supported pediatric device consortia. It is a **"free no-strings-attached" virtual accelerator** based at Texas Children's Hospital and Baylor College of Medicine that supports pediatric device innovators nationwide throughout the pediatric device life cycle.

HOW TO JOIN US

Fill out an intake form on swpdc.org/apply now, the SWPDC team will review the application and an intake call will be arranged by the team!

HOW WE CAN HELP YOU

Business

Business Plan Creation, Intellectual Property, Sources of Funding, Pitch Coaching, Startup Formation & Management

Medical

Market Submission Options, FDA-Compliant Manufacturing, Protocol Development, Biocompatibility Testing

Regulatory

Opinion Leaders in Pediatric Subspecialties, Extensive Networks of Physician Resources, Interview and Concept Validation, Design of Clinical Trials, PCI Meetings, Regulatory Consultants

SWPDC

Acceleration Resources

Concept

- **NSF Southwest I-Corps at Texas A&M, University of Houston, Rice:** Needs finding and validation program
- **TMC Pediatric Bio-design Fellows Program:** Concept generation & development
- **Texas A&M and Rice Student Capstone & Masters Projects:** Collaborative concept-to-prototype projects, Risk-based detailed design engineering/fabrication/testing (A&M Masters)
- **Rice Oshman Engineering Design Kitchen (OEDK):** Prototyping space available for Rice capstone students

Engineering

- **MinnHealth:** Contract design and manufacturing services
- **Fannin:** De-risking technology, prototype development
- **Biotex:** Industrial design, mechanical, electrical, optics, firmware, and software development

Preclinical

- **Proxima CRO:** Regulatory expertise and FDA interactions
- **Texas A&M Institute for Preclinical Studies (TIPS):** Large- and small-animal study support
- **Baylor College of Medicine Center for Comparative Medicine (CCM):** Large- and small-animal study support

Clinical

- **Proxima CRO:** Regulatory expertise and FDA interactions, Full-service clinical study support
- **Dan L. Duncan Institute for Clinical and Translational Research (ICTR) at BCM:** Admin support for grant submissions, BRAIN submissions, proposals review and editing, clinical studies
- **BCM Faculty Seed Grants:** Seed funding awards in collaboration with Baylor College of Medicine faculty

Manufacturing

- **Biotex:** Design verification and validation, clinical study builds, supply chain optimization
- **Proxima:** Quality, design history file support, and QMS
- **Cooper Consulting**: Design and development, testing and evaluation, compliance & safety
- **Texas A&M**: Device sterilization pilots (EtO/Ebeam), Injection molding development, Catheter devices

Marketing

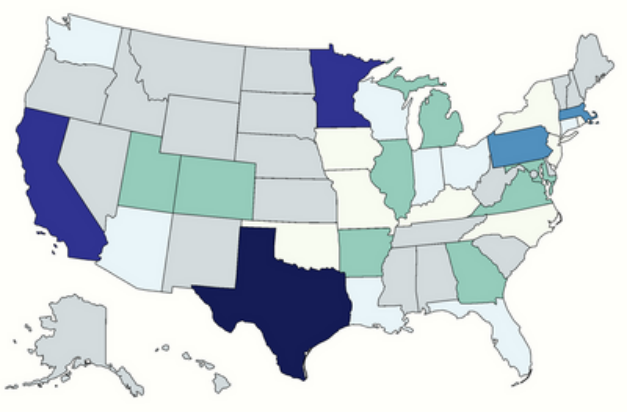
- **AAP SOATT, AAP SOU, RBPC, TNVC, Ignite:** Non-dilutive direct device funding
- **Bioscience Writers (BSW):** SBIR/STTR Grant Assistance
- **BCM Licensing Group:** Institution tech transfer
- **Reimbursement Consultants:** Network of vetted reimbursement consultants

Commercialization

- **Minneapolis Medical Alley:** Healthcare innovation network
- **Texas A&M Aggie Angel Network (AAN):** Early-stage tech investment network
- **TEES/A&M Office of Technology Transition:** IP management, venture creation for applied research, NSF-ICORPS training for pediatric devices
- **UH Technology Bridge Innovation Park**: Research facilities, networking opportunities, strategic location
- **Rice OwlSpark, UH Red Labs, TMC Innovation Accelerator, JLabs @ TMC, PDIC, Houston Exponential, Healthtech Arkansas, Ignite**: Accelerators and incubators

SWPDC

2024 SWPDC Impact



Supporting 271 pediatric device innovators in 29 states!

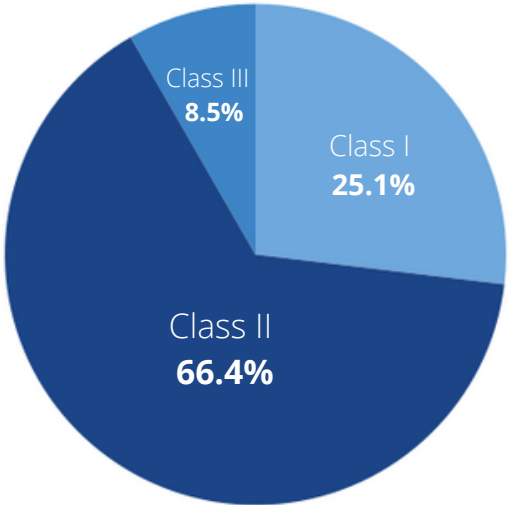
Our **Top 3** services include **PCI Meetings**, **Regulatory Consultants**, & **Clinical Collaborators**

32 Pediatric Subspecialties

14 Capstone projects at Texas A&M & Rice supported this year

Most Common Subspecialties
Cardiovascular & Pulmonary

Device Classifications



Pediatric Subpopulations Treated

Newborn/Neonate	Infant	Child	Adolescent
23.6%	18.6%	29.7%	28.3%

Stage of Development

Concept	Prototype	Preclinical	Clinical	Manufacturing	Marketing	Commercial Use
8.9%	40.0%	19.6%	15.6%	5.19%	3.33%	7.41%

Funding raised by SWPDC innovators
FY 2023 - 2024 : $41.1 M
Total: $259.8 M

Over **$200,000** in SWPDC funding awarded to **8** pediatric device innovators in FY 2023 - 2024

SWPDC

Opportunities

DIRECT DEVICE FUNDING

BCM Seed Funding for Pediatric Patients
Up to $25k in seed funding, Opens April - May
Support for pediatric device development & clinical trials @ BMC/TCH

BCM/TCH Capstone Projects
Number of projects funded vary, Opens April - May
Call for projects that address unmet needs with novel pediatric devices for the next academic year.

AAP SOU Pediatric Urology Price
Up to $20k in prizes, Opens August-September
Support for the development of pediatric medical devices in urology

AAP SOATT Pediatric Price
Up to $25k in prizes, Opens August-September
Support for the development of pediatric medical devices

Rice Business Plan Competition
Up to $25k in prizes, Opens March
Support for the development of pediatric medical devices awarded at the Rice Business Plan Competition

Texas A&M New Ventures
Up to $25k in prizes, Opens March
Support for the development of pediatric medical devices awarded at TAMU New Ventures Competition

Design of Medical Devices Conference
Prizes vary; Opens April
Support for the development of pediatric medical devices awarded at the University of Minnesota Design of Medical Devices Conference

PREVIOUS WINNERS

Freezenit, eNHance Diagnostics, EndoShunt, BWI Bridgeway Innovations, LLC, Halcyon Biomedical, NeuroBell, HERAbiotech, VPS Vascular Perfusion Solutions, KidTech, Inc., drio, Limbix, NeuraStasis, Ember Sleep, MiraHeart, imi Integrated Molecular Innovations, Luminoah, Pyrames, glimpse, Global Continence, AO, episLS, XNhealth, Pediatric Exo, Starling, Neurava, blue comet, HERO Medical, Solenic Medical, GoGo band, IndepENEMA, BIOSENSE, checkable, ZUTURIS, RELAVO, SLUMBERFLOW, HiPR Innovation, Vera Dermics

Real-World Evidence

Effects of Aorto-Pulmonary Shunts on Post Surgical Outcomes

Additional funding from the FDA PDC program supports the RWE Demonstration project of SWPDC, which is a collaboration between Texas Children's Hospital/Baylor College of Medicine and Texas A&M.

The current SWPDC RWE demonstration project aims to analyze historical cardiac intensive care unit data from a large group of pediatric patients with congenital heart disease (CHD) who have undergone aorto-pulmonary (AP) shunt placement. AP shunts are used to improve pulmonary blood flow in various CHD cases, but they carry a risk of thrombosis, which can lead to sudden cardiac arrest if pulmonary blood flow is interrupted. The project's objectives are to evaluate AP shunt performance, identify predictors of shunt occlusion in neonates with CHD, and create a predictive model for adverse events.

Leaders of this Project:

Ashish Ankola, MD
Texas Children's Hospital

R.Brandon Hunter, MD
Texas Children's Hospital

Balakrishna Haridas, Ph.D
Texas A&M University

Achu Byju
Texas A&M University

Current & Future Plans

We have also formulated 3 more RWE use cases in interventional cardiology, ECMO, and wearables monitoring for multistage CHD patients. These represent a diverse and healthy inventory of RWE projects for execution in future years. This past year has also included outreach efforts with other PDC sites to explore RWE collaborations. There was substantial participation by SWPDC PIs (Koh/Haridas) in symposia and meetings focusing on RWE topics, and associated collaborations/projects. Finally, the SWPDC team is in active discussions with several medical device companies to understand their needs in RWE projects and how they can leverage the SWPDC as well as other PDC sites to conduct these studies. An important consideration for our team in these efforts is also the need to ensure synergy with the national FNIH Pediatric Medical Devices Public Private Partnership (PMD-PPP) effort.

REAL-WORLD EVIDENCE PROGRAM

Baylor College of Medicine

Texas Children's Hospital

SWPDC

Featured Story

CobiCure Grants $2M to PolyVascular in SWPDC-Introduced Collaboration

Polyvascular is on a mission to redefine the treatment landscape for children with congenital heart disease. Their groundbreaking approach involves developing medical-grade polymer valves, offering a revolutionary alternative to traditional methods and potentially reducing the necessity for invasive procedures. This innovation holds the promise of transforming the lives of countless young patients.

In a recent milestone announcement, Polyvascular unveiled a strategic partnership with CobiCure, a nonprofit organization dedicated to advancing pediatric medical technologies. This collaboration brings $2 million in grant funding and invaluable advisory and strategic expertise. Polyvascular and CobiCure aim to accelerate the development and deployment of life-changing medical solutions for children facing rare and underserved conditions.

Central to realizing this collaboration is the crucial support SWPDC provides. SWPDC played a pivotal role in introducing Polyvascular to CobiCure, facilitating the forging of this partnership. Moreover, SWPDC's support extended beyond introductions. They provided Polyvascular with a letter of support, a key component in securing crucial funding. This support helped Polyvascular win the $2 million Small Business Innovation Research (SBIR) grant, further empowering their mission to revolutionize pediatric cardiac care.

Henri Justino, MD, Co-founder of Polyvascular

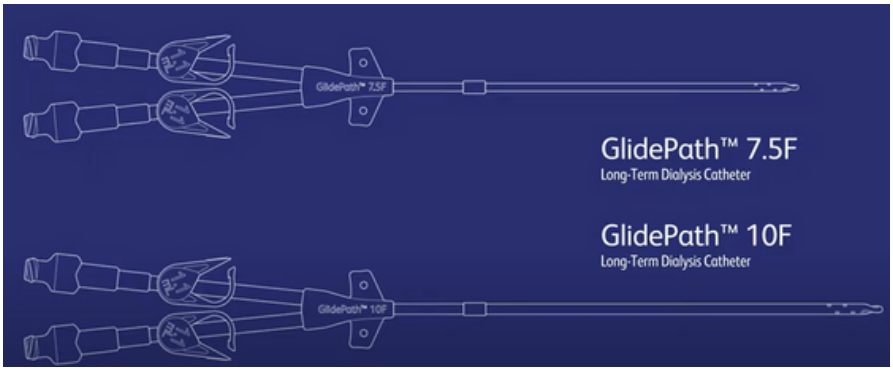
Expressing gratitude for this pivotal introduction and support, Will Clifton, MD, Chief Operating Officer at Polyvascular, acknowledges the vital role played by SWPDC. "Special thank you to Chester Koh, Christine Luk, and the rest of the SWPDC team for introducing us to CobiCure and forging this partnership!" says Dr. Will Clifton emphasizing the significance of collaboration in advancing their shared goal of enhancing pediatric cardiac care.

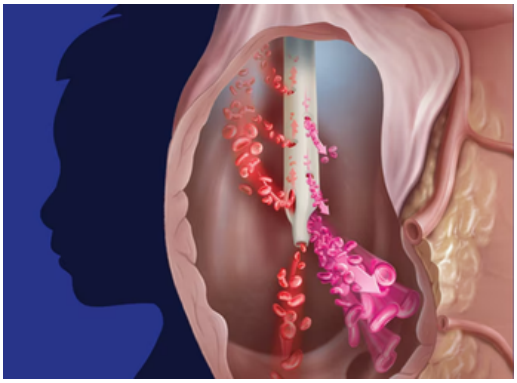
With the support of SWPDC and the collaborative efforts of Polyvascular and CobiCure, the journey towards eliminating repeat surgeries in children with congenital heart disease takes a significant stride forward. Dr. Clifton affirms, "With this partnership, we are one step closer to reaching this vulnerable population and improving their quality of life."

CobiCure PolyVascular SWPDC

External Innovation Efforts

Glidepath Pediatric Dialysis Catheters (BD/Bard)





SWPDC provides a la carte engagement for external companies/innovators seeking to access SWPDC services. SWPDC can effectively match external innovator needs and quickly connect them to the SWPDC ecosystem partner best suited to help the company.

The Glidepath Pediatric Dialysis Catheters (BD/Bard) is an example of a successful external innovation program. In conjunction with the 2018 SWPDC Annual Symposium and Business Meeting in Houston, Nate Smith (product manager) and Niki Hale (R&D program manager) participated in SWPDC key opinion leader meetings with TCH/BCM pediatric nephrologists, surgeons, and interventional radiologists to obtain feedback on a pediatric dialysis catheter in early development. This BD/Bard group is one of the few industry groups focused on innovations in pediatric devices. As a result of these meetings, BD/Bard completed the development of the GlidePath long-term dialysis catheters with pediatric sizes and shorter lengths that met the needs of pediatric patients. In May 2020, BD/Bard received 510(k) clearance for these new pediatric hemodialysis catheters.

With an increased emphasis on assisting later-stage development, we expect increased participation from our industry Advisory Board members and both current and newly added industry partners, including those in the Minneapolis region, such as Medtronic and other Medical Alley participants.

BD Baylor College of Medicine Texas Children's Hospital SWPDC

Impact Narratives

AbiliTech Medical (Houston, TX) developed the AbiliTech Assist, an innovative in-home device designed to support elbow and shoulder function for pediatric patients with neurologic conditions. A participant in the 2019 TMC Accelerator cohort, AbiliTech received a BCM Faculty Seed Grant from SWPDC in 2020, awarded to Dr. Aloysia Schwabe, to conduct a clinical study on improving upper limb mobility in pediatric patients with cerebral palsy. Since 2021, AbiliTech has successfully raised investor funding and advanced to commercial availability.

Bardy Diagnostics, part of the SWPDC portfolio, developed an advanced wearable cardiac monitor designed to enable ambulatory cardiac monitoring in children. In 2019, Bardy received SWPDC's $25,000 direct device funding award during the SXSW Impact Pediatric Health (IPH) competition, alongside support from other Pediatric Device Consortia such as NCC-PDI. This innovative technology gained significant traction and recognition, ultimately leading to Bardy Diagnostics' acquisition by Hillrom in 2021.

Berlin Heart® EXCOR Pediatric Ventricular Assist Device (Houston, TX) is a blood pump that vibrates rhythmically to assist children whose natural hearts are unable to pump enough blood. In 2011, the Berlin Heart was approved by the FDA for use in children after a comprehensive study on the safety and probable benefit of the pediatric heart pump, led by TCH/BCM, in cooperation with 17 hospitals. Robert Kroslowitz, Berlin Heart's CEO for North America, serves on the SWPDC Advisory Committee.

Bivacor (Houston, TX) developed the Bivacor Total Artificial Heart (BTAH), a long-term cardiac replacement device to fully support heart function in pediatric and adult heart failure patients. Featured in SWPDC's Pediatric Device Innovators Forum #5, the device highlighted challenges and advancements in pediatric and fetal surgical device development. In December 2023, Bivacor received FDA IDE approval for a first-in-human early feasibility study at 10 hospitals, including the Texas Heart Institute, targeting biventricular heart failure patients as a bridge to transplantation. Pediatric trial efforts continue at Texas Children's Hospital under Dr. Iki Adachi.

Impact Narratives

Rhaeos (Chicago, IL), a female-led startup from Northwestern University developed Flowsense, a wireless, wearable sensor for monitoring pediatric hydrocephalus shunts. SWPDC awarded Rhaeos $25,000 in direct device funding at the 2019 Rice Business Plan Competition and supported their participation in the 2020 TMC accelerator cohort. Additionally, SWPDC provided regulatory consulting that led to Breakthrough Device Designation in June 2020 and guided reimbursement strategy. In February 2023, Rhaeos closed a Series A financing round and is now conducting a 10-center pivotal study to secure FDA de novo marketing authorization.

Prapela (Biddeford, ME) developed a stochastic vibration stimulation device for infants with neonatal abstinence syndrome (NAS). SWPDC awarded Prapela $25K in direct device funding through the 2019 SXSW IPH competition 2019 and introduced them to the seven children's hospital event sponsors. Prapela was a previous winner of the JLABS Next-Gen Baby Box Quickfire Challenge and also received direct device funding from NCC□PDI. They have received follow-on funding and multiple NIH SBIR grants. They were awarded FDA Breakthrough Device Designation for NAS in late 2019 and for apnea of prematurity in early 2023.

Pyrames (Cupertino, CA) developed the Boppli sensor for noninvasive blood pressure monitoring of neonates with assistance from multiple PDCs. After joining the SWPDC portfolio, Pyrames participated in the 2019 TMC accelerator cohort, received $25K in SWPDC direct device funding via the 2020 SXSW IPH competition, and received another $25,000 as a recipient of the SWPDC's AAP SOATT Pediatric Device Prize. They also got regulatory support via Proxima that led to an FDA Breakthrough Device Designation in May 2020. This regulatory support also contributed to Pyrames announcing FDA clearance of the Boppli device as a 510(k) Class II medical device in September 2023.

Visualase (Houston, TX) is an MRI-guided laser ablation technology for minimally invasive neurosurgery in adults and children, developed by Biotex (Dr. Gowda, SWPDC Advisory Committee) and Texas A&M. The pediatric neurosurgical clinical trials for this device were conducted at TCH/BCM with Dr. Daniel Curry, leading to FDA regulatory approval. Visualase was acquired by Medtronic in 2014.

Conference Highlights

9th Annual Evening of Pediatric Device Innovation

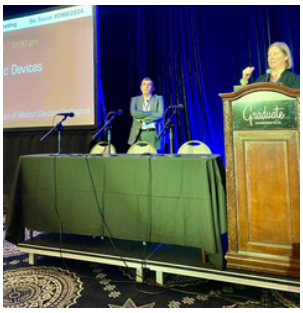
Thursday, December 7, 2023

SWPDC's annual pediatric device innovation event highlighted SWPDC's five-year roadmap through a keynote by Dr. Gwen Fischer, a panel discussion, and a networking reception to foster collaboration in pediatric healthcare.

Design of Medical Devices Conference

Tuesday, April 9, 2024

Dr. Chester Koh and Dr. Balakrishna Haridas represented the SWPDC as keynote speakers at the University of Minnesota's Design of Medical Devices Conference, focusing on bridging the innovation gap in pediatric medical devices and improving patient access through collaboration among healthcare providers, inventors, and engineers.



Pediatric MedTech CEO Summit

Tuesday, November 12, 2024

The SWPDC team attended the Pediatric CEO Summit, sponsored by CobiCure and founded by Impact1, to connect innovators in pediatric medical device development. The event featured experts sharing insights and fostering collaboration in pediatric MedTech. Dr. Balakrishna Haridas moderated a Pre-clinical Testing panel with Greg Kaluza from CRF Skirball Center for Innovation and Parker Tyler from Edwards Lifesciences.

Contact Us

Get in touch

6701 Fannin Street,
MWT Suite 620
Houston, Texas 77030

southwestpdc@bcm.edu

832-822-3160

linkedin.com/company/swpdc/

www.swpdc.org

Send us a message

https://swpdc.org/contact-us/

Subscribe to our newsletter from the website to receive SWPDC updates and opportunities