Pediatric Medical Devices Assisted by PPDC: Advanced Registry

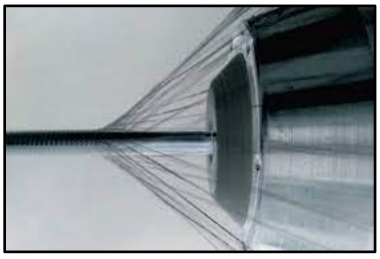
Anesthesia

TrachAlarm™

Innovations Unlimited LLC, of Pennsauken, NJ, is a women owned business creating the TrachAlarm™ to alert pediatric caregivers in a home care or other non-hospital setting if a patient's tracheostomy tube becomes dislodged. Tracheostomy tubes allow patients to breathe while undergoing treatment for certain chronic and congenital diseases. Fast recognition of tracheal dislodgement reduces risk for complications such as hypoxia, respiratory failure, cardiac arrest, and death. In addition to the PPDC funding, which it received in 2019, Innovations Unlimited also received $220,000 in Phase I SBIR funding to assist with receiving FDA clearance of the TrachAlarm™.

Cardiovascular

Bioabsorbable Flow Diverter

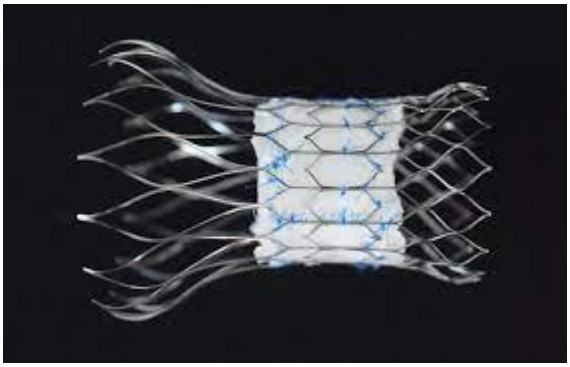


Pegasus Therapeutics is combining the latest technology in non-surgical aneurysm treatment and coronary artery stenting to design a bioabsorbable flow diverter, that will give the body time to heal and then dissolve away. In 2015, Pegasus Therapeutics received PPDC support in the form of advisement. The company has acquired over $50,000 from various donors and financial sources.

PeriPath

PeriCor LLC, has developed the PeriPath for pediatrics, which is a novel access tool that replaces the need for open heart surgery by allowing for a single-incision, percutaneous entry. This less invasive procedure reduces procedure time, pain, length of stay and complications. The PeriPath consists of two working channels that allow for simultaneous insertion of therapies (pacemakers, needles, defibrillator lead) with a rigid thoracoscope for direct visualization of the procedure. PeriCor received direct PPDC device funding in 2020. In 2022, PeriCor received a Phase II SBIR grant from the NIH, totaling $1.8 million over two years, to examine the use of the PeriPath in pediatric patients.

MASA VALVE



PECA LABS was founded in 2012 as a spin-off company based on technology developed from **McGowan Institute** investigators at Carnegie Mellon and the University of Pittsburgh. The company has developed the MASA valve, which is the first fully synthetic transcatheter valve. With indications for the pediatric patient population, the MASA valve could provide an efficient prosthetic heart replacement strategy for patients with Tetralogy of Fallot, transposition of the great vessels, and pulmonary atresia. The PPDC introduced PECA to pediatric cardiac surgeons, who provided feedback to PECA regarding the need for the device and its clinical feasibility. The PPDC, along with experts

at CHOP, helped PECA Labs to develop clinical protocols and a clinical trial agreement with CHOP for the IRB submission, ahead of an FDA review. At present, the MASA valve is in clinical trials to conduct early feasibility studies.

TxGuard

Annoviant LLC is a company that is based on technology, developed at Clemson University, which intends to fabricate pulmonary valved conduits that can grow with the patient. This innovative technology would reduce the need for additional interventions to replace valves in a growing pediatric patient. Annoviant received PPDC funding in 2020. In 2021 the company was awarded an SBIR phase II grant for $1,850,000. The funding will be used to pursue preclinical studies to assist in the FDA approval of this Class III device.

Self-regenerating Pulmonary Valve

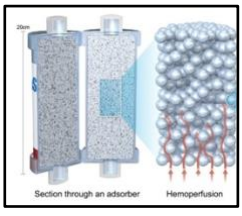
Neoolife, spun out of the **McGowan Institute** of the University of Pittsburgh, is pursuing novel tissue engineering approaches to fabricate heart valves. They use polymeric scaffolds that have the ability to foster tissue growth and allow for in-situ tissue regeneration. This technology would eliminate the need for mechanical and animal-derived tissue heart valves. In addition, the tissue engineered approach would allow for the valve to grow with the patient, which is invaluable for pediatric patients. Neoolife received PPDC direct device funding in 2020. Recently the company has received the prestigious Consolidator Grant from the European Research Council, which has a total cash value of $2,000,000. They have also acquired additional private funding, totaling over $650,000, to support preclinical studies to assist in gaining FDA approval for this Class III device.

Critical Care Medicine

EyeBOX

Oculogica Inc., of New York City, was supported by the PPDC, in 2018, for the development of the EyeBOX, an eye-tracking based test to noninvasively and instantaneously assess intracranial pressure (ICP) in under four minutes. Quick and accurate detection of increased ICP in children following a traumatic brain injury would facilitate timely treatment and prevent further injury. The EyeBox received FDA clearance in January 2022 and is currently commercially available.

Hemosorb



Dr. Nahmah Kim-Campbell of the Children's Hospital of Pittsburgh and the **McGowan Institute** developed an extracorporeal hemoperfusion device that achieves selective cell-free plasma hemoglobin (PHb) removal from whole blood via a column containing small porous beads (diameter ~100 µm) with haptoglobin immobilized on the bead surface. In 2020 the PPDC recommended the Hemosorb for **Archimedic** early-stage support, and the device is undergoing a pediatric scale prototype development.

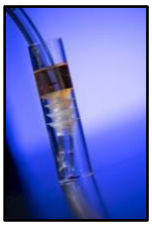
Infrascanner

InfraScan Inc., founded by Philadelphia's Baruch Ben Dor, developed Infrascanner, that is a portable device that uses near-infrared technology to screen patients for intracranial hematomas, which is invaluable for identifying those patients who would most benefit for immediate referral to a CT scan and possible neurological intervention. InfraScan Inc received European CE regulatory approval in 2008 and US FDA clearance for use in hospitals on adults was obtained in 2013. With assistance from PPDC, in 2017, a clinical trial was conducted at CHOP to expand the FDA clearance and to show the efficacy and safety of the Infrascanner in children. Pediatric labeling was approved 2022 and the Infrascanner is now commercially available for pediatric applications

LifeFlow Rapid Infusion System

410 Medical Inc. are the makers of the LifeFlow Rapid Infusion System, which is a hand powered infuser to quickly deliver fluids to critically ill patients. 410 Medical received PPDC direct device funding in 2017 to help fund investigations into the use of the LifeFlow for rapid blood infusions in the pediatric patients, for which it received FDA 510(k) clearance in November of 2020. The product is now on the market and available.

NextGen Endotrachial Tube



Respair Medical is a **University of Pittsburgh** medical device spin-out company that builds innovative airway products to support clinicians and patients in a critical care environment. The NextGen ET is a novel simplified endotracheal tube that creates an effective seal without a balloon cuff and delivers better airflow to pediatric patients. The cuffless, baffled design maximizes the tube to airway ratio while securely sealing the airway, reducing aspiration risk. Respair Medical worked with Archimedic for prototype development. They have received over $150,000 in follow on funding.

Precynge

Assure Technologies LLC, of Chapel Hill, NC, received support for the Precynge device to provide consistently accurate small volume medication measurements critical to pediatric care. Neonatal and early pediatric patients are particularly vulnerable to dosing errors; exposure to potential adverse drug events occurs three times more frequently in pediatric than in adult patients. While the majority of IV doses are made in the pharmacy, nurses frequently prepare IV push medications at the bedside for small volumes in neonatal and pediatric patients, especially for high alert medications like narcotics and insulin. In 2022, Assure Technologies received PPDC funding for prototype development. The company has since received an additional $50,000 in funding to assist in bringing this Class I device to market.

Respiratory Function Monitor

Nihon Kohden Corporation, a Japanese based company, has a portfolio of diagnostic and monitoring devices across a wide range of clinical specialties. In 2014, the PPDC assisted Nihon Kohden by providing clinical feedback about their respiratory function monitor. The PPDC also arranged for meetings with the project engineer and a team of clinicians. The results of these meetings informed the company that a product redesign was necessary for the device to be useful in the pediatric patient population. At the present, the device is undergoing prototype development. Nihon Kohden is publicly traded on the Tokyo Stock Exchange.

Small Volume Manufacturing of Pediatric Ventilation Devices

Actuated Medical is currently working with the Children's Hospital of Philadelphia to use additive manufacturing to provide patient specific, custom designed CPAP masks for neonatal patients. At present, respiratory masks for very young patients, or those with facial dysmorphia, are ill fitting and less than ideal jury-rigged solutions must be employed to ensure a tight seal. CHOP investigators and Actuated Medical scientists and engineers are working together to use high level facial imaging along with 3-D printing to fabricate properly fitting CPAP masks. In addition to the PPDC direct device funding, which was awarded in 2020, this project has received an additional $1,460,000 in funding through a NICHD Fast Track SBIR Phase I/II grant award platforms.

TubeClear

Actuated Medical has developed the TubeClear device. TubeClear aims to reduce interruptions to feeding and medication regimens for the patient, reduce the time healthcare practitioners spend on hardware issues, and save significant time and money by quickly restoring patency to occluded feeding tubes. TubeClear is comprised of a reusable Control Box paired with a single use Clearing Stem. The healthcare practitioner attaches a Clearing Stem to the Control Box and inserts the Stem a few centimeters into the tube. Then the healthcare practitioner turns on the Control Box and manually directs the Clearing Stem further into the tube. The Clearing Stem has a specially designed tip that moves in a forward and backward motion that chips away at the clog to restore patency. TubeClear helps the healthcare practitioners to rapidly clear the tube without the expense and risk of tube replacement. The system is FDA cleared and CE Marked specific to NE, NG, G and J feeding and decompression tubes for adult patients. The PPDC offered assistance to Actuated Medical by organizing a clinical trial at CHOP, that included identifying a Principal Investigator for the CHOP trial and helping to arrange for a clinical research coordinator through the CHOP Clinical Trials Office. PPDC also assisted in developing an IRB protocol and in the FDA pre-submission process.

TwistJect™

In 2021, **SOLUtion Medical** of Philadelphia, was awarded direct device funding from the PPDC to assist in the development of the TwistJect™, a device that enables caregivers to manage children during an adrenal crisis. Adrenal crisis is a life-threatening condition resulting from insufficient levels of the hormone, cortisol. Children and adolescents experience some of the most severe morbidities of all patients who experience adrenal crisis due to the difficulties in managing adrenal insufficiency in younger populations and the difficulties in providing rescue injections. The TwistJect™ is a one-step delivery device that reconstitutes hydrocortisone sodium succinate and removes all entrapped air in one user step. SOLUtion Medical, a women owned and operated company, has raised an additional $1,000,000 in funding for preclinical studies.

Dermatology

CLENS

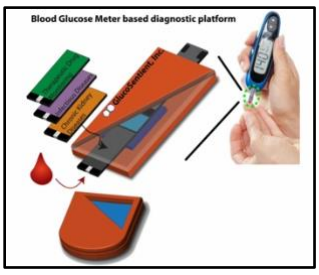
PhotoSonix Med has developed the CLENS which uses light and ultrasound to treat chronic bacterial infections. Severe acne affects up to 20 million teens and adults. In 2014, the PPDC reviewed the technology with experts and clinicians for clinical and scientific feasibility, and provided advice for product improvement. PhotoSonix Med has raised $849,000 for prototype development, and the company is a founding member of the PLEXUS Healthcare Innovation Hub in Philadelphia.

Diagnostic

Cough Collector

Deton Corporation specializes in development and marketing of medical devices to assist with non-invasive sample collection for the diagnosis of lower respiratory infections. In 2016, the company received PPDC support in the form of expert advice, and introductions to thought leaders in the pediatric respiratory space to bring the Cough Collector to the pediatric market. In 2017, Deton was awarded a Phase I SBIR grant to investigate the utility of the Cough Collector design for use in a pediatric population to capture airborne bacteria directly from a cough to facilitate rapid diagnosis of infection. They have since received $825,000 in funding to advance this technology. The Cough Collector is currently in prototype development.

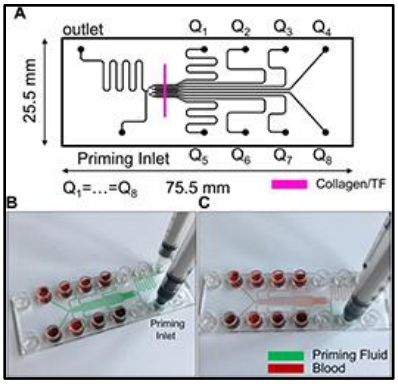
Diabetes Insipidus Monitor



GlucoSentient is developing a range of metabolomic monitoring systems that are based on using their Blood Glucose Meter (BGM) as a platform for additional diagnostic endpoints. In 2017, the PPDC assisted the company in their device to monitor sodium levels to address diabetes insipidus. GlucoSentient has acquired $90,000 for prototype development for the use of the BGM platform as a diabetes insipidus monitoring device. In addition to their entry in the diabetes

insipidus space, GlucoSentient has raised over $2,000,000 in SBIR funding for other applications related to their platform technology.

Point-of-Care Rapid Platelet Function Testing



FloBio LLC, of Philadelphia, founded by Penn Engineering Professor Scott Diamond, is developing a novel, point-of-care microfluidic chip and reader for rapid platelet function testing. Using minimal amounts of blood, the device will monitor anticoagulation pharmacology used in newborns undergoing corrective heart surgery or on life-sustaining circulatory or pulmonary support. The device will help to control thromboembolic events in infants and children suffering from congenital heart defects. Funded by the PPDC in 2019, FloBio has received an additional $3,000,000 in SBIR grant funding from the NSF (Phase 1) and NIH (Phase 2) to conduct preclinical testing.

ENT

Bacterial Sinusitis Detection Device

ENTvantage Diagnostics of Austin, Texas, is developing a device to improve the accuracy of diagnosis of sinusitis (sinus infections). Although bacteria cause sinusitis only about 10 percent of the time, physicians commonly prescribe antibiotics, which are ineffective against non-bacterial sinusitis. Because diagnostic tools are not currently available for a proper diagnosis, clinicians have to rely on imprecise diagnostic algorithms based solely on the patient symptoms. ENTvantage aims to create a point-of-care assay device for pediatric use to provide rapid results that are simple to interpret with ease of use and minimal staff training. In a manner similar to that of rapid influenza A and B tests commonly used in primary care clinics, this new device is envisioned to reduce unnecessary antibiotic usage. In 2015, ENTvantage received direct PPDC support. The company has also received an additional $2,160,000 of funding. As of November 2021, the company has been conducting multicenter clinical trials to gain FDA 510(k) clearance of the bacterial sinusitis detection device.

Otitis Media Detection Device

OtoNexus Medical Technologies Inc. is an early-stage woman-led company that is developing a handheld Doppler ultrasound medical device to rapidly and accurately diagnose middle ear infections, called Otitis Media (OM), in children and adults. Otitis Media is the most frequent indication for antibiotic prescriptions in children. 17.6 million patient visits each year are coded to OM at a cost of more than $5 billion/year, yet clinical studies show a 50 percent error rate in diagnosis. Current diagnostic methods are decades old and cannot distinguish the type of infection behind the eardrum. With funding in part from the PPDC, received in 2014, along with additional funding totaling $7,749,610, OtoNexus is acquiring preclinical data to assist in obtaining FDA clearance.

Gastroenterology

Pediatric PUMA-G

Coaptech of Baltimore, MD, is developing the Pediatric PUMA-G, which is expected to provide a safer way to place feeding tubes for children. Gastrostomy tubes (G-tubes) provide a path for nutrition delivery directly into the stomach, bypassing the mouth and esophagus, for patients who have difficulty swallowing. Traditional technology used in these procedures cannot "see through" tissue, and G-tube malposition causes acute harm and other complications. The alternative fluoroscopic approach requires the use of ionizing radiation, which presents serious long-term risk of cancer. The use of ultrasound imaging is expected to make the Pediatric PUMA-G safer, timelier, and less costly than conventional G-tube placement methods used in children. Having received FDA clearance for the use of PUMA-G in adults, in 2022 Coaptech received PPDC direct funding to conduct preclinical analysis to received FDA clearance for use in the pediatric patient population. They have subsequently received $1,767,000 additional funding.

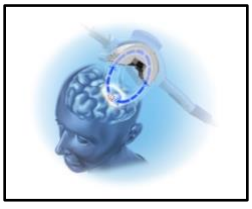
General Hospital

SafeBoard

SafeBoard LLC, of Youngsville, LA, is creating SafeBoard, a patented extremity stabilization device designed to assist in the placement of ultrasound-guided PICC lines and IV catheters in neonates and children. Historically, repeated unsuccessful venipunctures and use of general anesthesia and sedation can be traumatic and dangerous to both the patients and their caregivers. SafeBoard aims to minimize the amount of time it takes to successfully insert a PICC/IV in a child, minimize needed personnel, reduce the use of medications, minimize discomfort, and decrease the rates of catheter-related complications. The project received direct device PPDC funding in 2022 and is currently in clinical trials.

Mental Health

NeuroStar Transcranial Magnetic Stimulation (TMS) Therapy



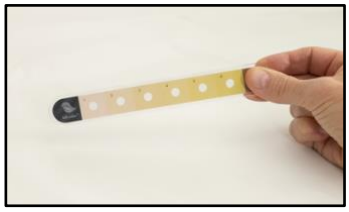
The NeuroStar TMS Therapy, from **Neuronetics Inc.**, is an FDA cleared non-drug, non-invasive treatment for depression. In 2014, the PPDC assisted the company by facilitating interactions with the FDA for advice on regulatory guidance. In 2022, the device was cleared by the FDA for adult anxiety and depression treatment. At present, Neuronetics Inc. is conducting clinical trials in adolescent patient populations to apply for FDA clearance for that age group. Neuronetics Inc. is a publicly traded company on the NASDAQ stock exchange.

Neonatology

bili-hut™

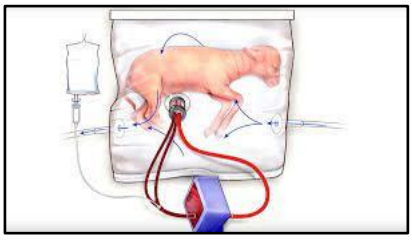
Little Sparrows Technologies is a woman led Massachusetts based company that addresses the issue of jaundice in the neonatal patient population. About 8 percent of all newborns have severe neonatal jaundice. It's one of the most common conditions affecting infants, and the incidence jumps to 80 percent for preterm newborns in the first week of their lives. An estimated 6 million newborns worldwide do not receive treatment for severe jaundice because they lack access to effective phototherapy devices. Annually, jaundice causes an estimated 30% of newborn deaths in underdeveloped areas, and many survivors suffer lifelong neurological disability as a result of the disease. The bili-hut™ is a portable, high-intensity phototherapy device for treating newborns with neonatal jaundice. Little Sparrows Technologies offers a three-pound, collapsible enclosure that uses low-energy- requiring LED lights, enabling use with either line power or alternative sources such as a 12-volt battery. Support for this device includes funding from the PPDC (2014) combined with other funding sources, including the Saving Lives at Birth Grant Competition. In 2018, Little Sparrows Technologies won the Patents for Humanity Award for bili-hut™. Patents for Humanity is the US Patent and Trademark Office's (USPTO) awards competition recognizing innovators who use game-changing technology to meet global humanitarian challenges. The bili-hut™ is now commercially available.

bili-ruler™



Little Sparrows Technologies is a leader in developing innovative solutions to address jaundice in neonatal patients. The bili-ruler™ is an icterometer showing a series of yellow swatches of increasing intensity that correlate to ranges of serum bilirubin levels and help determine the severity of jaundice. This simple, handheld device allows a frontline health worker to assess jaundice in a pediatric patient. PPDC direct device funding, combined with an additional $265,000 of funding from additional sources, has helped Little Sparrows acquire the necessary validation data to further advance this Class I device.

Extracorporeal Support of the Premature Infant (ESPI)



Dr. Alan Flake of **CHOP** has been at the forefront of developing and advancing the concept of an artificial placenta to help in the survival and development of premature infants. The ESPI device serves, as an artificial placenta, to bridge the gap between the mother's uterus and the world. In 2014, the PPDC facilitated interactions between NAMSA and Dr. Flake's team and by assisting in a Pre-Submission meeting with the FDA, after which the FDA provided guidelines for preclinical studies that could lead to regulatory approval. The PPDC also introduced Dr. Flake to Archimedic to assist in prototype development. The ESPI project is currently in preclinical studies and has been supported by more than $5,000,000 in funding from a variety of sources.

Neoneur

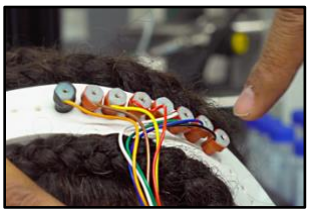
Neoneur LLC, of Pennington, NJ is a woman owned and operated company that is developing the Neoneur, a telehealth-enabled device that provides objective measurements of infants' oral feeding capability and developmental status. An infant's feeding skills consist of patterns driven by the brain to enable adequate nutrient consumption and respiratory protection at the same time without hindering growth. All infants must have feeding skills to thrive, but currently clinical observation is the only means to assess them. The Neoneur will enable the ability to monitor feeding and skill development for at-risk infants both in the hospital and through telemedicine at home to enable earlier discharge, decrease readmissions, and aid in early identification of developmental issues. Neoneur received PPDC direct device funding in 2021, which was used to assist the company in successfully receiving NIH funding of $1,900,000 in the form of a fast tracked, combined SBIR phase I and phase II award. The funding will be used for clinical trials.

SnugLit

TheraB Medical is a woman owned and led pediatric startup located in Michigan that is developing the **SnugLit**, a wearable infant swaddle that treats neonatal jaundice with phototherapy. Neonatal jaundice affects 2.4 million infants in the United States and as many as 20 million globally. The most common treatment involves light therapy systems, which require constant monitoring by nursing staff and cause prolonged separation of mother and child. With SnugLit, babies no longer need to be separated from their parents during phototherapy, but instead can receive complete treatment in the arms of their caregivers. In addition to the PPDC funding that TheraB Medical received in 2021, the company received an additional $1.3M seed round funding. The funding was used for completing final product development and manufacturing plans, and reaching 510(k) clearance.

Neurology

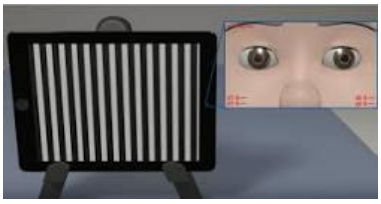
A quick-apply system for pediatric EEG



Precision Neuroscopics, a Pittsburgh based company that was introduced to the PPDC via the **McGowan Institute**, has developed a novel quick-application EEG system for pediatric patients which will make utilization of EEG recording more feasible and less invasive for children, ultimately increasing yield of EEG studies and therefore improving patient outcomes. Precision Neuroscopics was awarded direct PPDC funding in 2020. In 2022 they won the highest award of $150,000 in the UpPrize competition, an innovation challenge funded by the BNY Mellon Foundation of Southwestern Pennsylvania to support ideas and tech-based solutions that address societal issues.

Ophthalmology

Digital Platform to Identify Vision Acuity Impairment



Vifant LLC, of Philadelphia, is developing a digital platform that identifies vision acuity impairment in preverbal children. Waiting to treat visual impairment until children are old enough to verbally communicate may result in reduced early learning development or blindness. This device could enable physicians and parents to be proactive about their child's vision health without the need for verbal communication with the child. Vifant received PPDC funding in 2018. It has also acquired over $225,000 in additional funding for prototype development of this Class I device.

Orthopedics

DE-AFO

Developed by Ahad Behboodi, Ph.D. **at the University of Delaware (DE)**, the DE ankle-foot orthosis (DE-AFO) is a compact and comfortable smart ankle orthosis for children with cerebral palsy (CP), to help them walk more easily and for longer distances. The DE-AFO received PPDC direct support funding in 2020. In addition, they have received over $550,000 in funding through such institutions as the University City Science Center and the NSF. At present the DE-AFO is undergoing preclinical testing.

Dynamic Hip Stabilization Tether

McGowan Institute investigators have developed the Dynamic Hip Stabilization Tether for developmental dysplasia of the hip (DDH). DDH is the incorrect development of the hip joint, which can lead to abnormal gait, decreased strength, and increased rate of degenerative hip and knee joint diseases. This project plans to create a surgically inserted tethering device to improve outcomes of hip stabilization surgery on pediatric patients. The project received PPDC direct device funding in 2020 and has raised an additional $50,000 for preclinical testing.

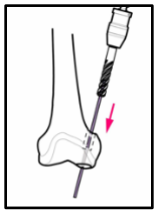
Wrex Magic Arms

The Wilmington Robotic Exoskeleton (Wrex) Magic Arm is a 3-D printed device, composed of elastic bands and attachment points, that allows patients with muscular and/or joint abnormalities to acquire use of their arms and legs. The PPDC, along with the PPDC Regulatory Advisor, Dr. Seth Goldenberg, met with the inventors at **JAECO Orthopedic** to discuss reimbursement and regulatory pathways. The project team also met with the Chief of the Division of Physical Medicine and Rehabilitation at CHOP to discuss a proposed outcomes study for the device. The company has received $65,000 in funding.

MyoPro Motion K

The MyoPro Motion K is a 510(k) exempt class II powered orthotic device, developed by **Myomo Inc.** (Boston, MA), to assist with motion and function in children with neuromuscular disorders. Originally developed at MIT with Harvard Medical School, the MyoPro arm and hand orthosis device functions by reading the faint nerve signals from the surface of the skin and then activating small motors to move the limb as the user intended. Funded by the PPDC in 2016, Myomo, Inc has been a publicly traded company (NYSE:Myo) since 2018 with an evaluation of $58 million.

Osteochondritis Dissecans Drilling & Fixation Device



Dr. Michael McClincy of Children's Hospital of Pittsburgh was identified by the **McGowan Institute** for support of his novel hybrid drilling system to treat osteochondritis dissecans (OCD) lesions. This system utilizes a single transarticular pin, placed under arthroscopic visualization with a custom jig guide, to mark the geographical center of the OCD lesion. This pin is then positioned with a cannulated drill bit to allow retrograde access for novel drill guide with variable pitch drill tunnels to enable circumferential drilling of the OCD lesion in a retrograde manner without fluoroscopic guidance. The PPDC supported Dr. McClincy in 2019 by entering his project in the **Archimedic** early-stage development program. At present, the technology is in prototype development.

Polymer-Based Liner for Prosthetic Sockets

RasLabs, a Boston based company, is developing, fabricating, and distributing customized products that have the potential to heal and save lives. They produce Synthetic Muscle, electroactive polymer (EAP) based materials and actuators that contract and expand at low voltages. This EAP technology could improve the interface between a child and his/her prosthetic limb. Without using gears or motors, the material contracts or expands comparably to muscle, in response to low-voltage electricity. Using this biomimetic material to line the socket of a pediatric-sized artificial leg or other limb could provide a snugger fit of the prosthetic device during normal daily use and improve a child's experience using it. In addition to the PPDC funding (2014), in 2017 Ras Labs received the NSF Phase 1 SBIR Award to investigate the feasibility of incorporating our Synthetic Muscle™ EAPs into prosthetic liners to provide for continual perfect fit throughout the day for amputees, with excellent results and another scientific breakthrough in our EAP technology. RasLabs has acquired over $605,000.00 of additional support from the Synthetic Muscle Project from the US Department of Energy, MassChallenge, Center for Advancement for Science in Space (CASIS), and US Department of Defense. The prosthetic liner device is in preclinical development.

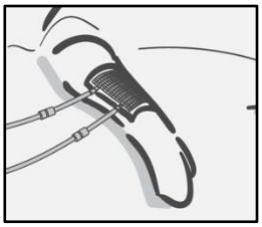
Second Generation Vertical Expandable Prosthetic Titanium Rib (VEPTR)

The VEPTR is used by orthopedic surgeons to treat thoracic insufficiency syndrome (TIS), which is defined as a range of chest wall deformities occurring as congenital defects that critically impact a newborn's or infant's respiratory function and lung growth. The VEPTR was first developed by the late Dr. Robert Campbell, when he was an orthopedic surgeon in San Antonio, Texas. The first non-investigational use of the VEPTR happened in Europe in 1994. It was not approved for use with a Humanitarian Use Designation in the United States until 2004. In 2009, Dr. Campbell joined **CHOP** as the director of the Center for Thoracic Insufficiency Syndrome. Dr. Campbell passed away in 2018, and in recognition for his outstanding contributions, the Children's Hospital of Philadelphia CTIS was renamed the Wyss/Campbell Center for Thoracic Insufficiency Syndrome. Dr. Patrick Cahill is the center's current director where he continues Dr. Campbell's legacy by improving upon the design and implementation of the VEPTR. The PPDC has facilitated these efforts by arranging meetings between industry leaders, such as Johnson & Johnson, and Dr. Cahill.

Other

Active Wound Dressing

Dr. Jorg Gerlach of the University of Pittsburgh's McGowan Institute developed a therapeutic concept of "dialysis in the wound," with a well-distributed (via decentral artificial capillary supply) high-performance (perfusion and recirculation pump supported) mass exchange. This device can allow on-wound milieu regulation and local factor perfusion through a capillary network of artificial semi-permeable hollow fiber membranes in the dressing; these micro-capillaries temporarily replace the patient's malfunctioning wound microcirculation. With the help of the PPDC, Dr. Gerlach received **Archimedic** support in 2020. This technology is currently undergoing prototype development for pediatric use, including market strategy development.



AlgometRx novel device for measuring and managing pain

AlgometRx is a spin off company from Children's National Hospital. The company is developing novel technology to measure and manage pain in patients of all ages. The current standard of care for pain assessment uses subjective scales such as the Visual Analog Scale. This approach is mechanism agnostic and fails to classify the pain's etiology or help guide a specific intervention. AlgometRx's novel technology and algorithms analyze pupillary dilation in response to neuroselective stimulation to formulate a nociceptive profile. This new construct is used to characterize pain type, intensity and assess the pharmacodynamic impact of analgesics. The PPDC recognized AlgometRx for early stage assistance through collaboration with **Archimedic**. AlgometRx has since acquired extramural funding, in excess of $300,000, through SBIR grants and private funding platforms.

OsteoAccess Jr.

A bone access system proposed by **Actuated Medical**, of Bellefonte, PA, aims to reduce patient discomfort, improve the success rate for first-attempt samples, reduce clinician fatigue, and shorten procedure times for bone biopsy and bone marrow aspiration procedures. Physicians performing these procedures on children currently face multiple challenges. This patient population requires deep sedation or anesthesia to tolerate bone access procedures. Children also have small, curved bones, which increase the risk of needle slippage and damage to surrounding tissue. The lack of CT or other image guidance during pediatric bone access increases the difficulty of maintaining the desired needle trajectory, which results in failed access and repeated insertions, as well as increased post-operative pain and risk of infection. This new device under development will reduce insertion force and needle slippage, allowing for faster and more reliable bone penetration. In 2015, Actuated Medical received direct device funding from the PPDC to assist in the development of the OsteoAccess Jr for pediatric use. In addition, funding up to $5,657,000 is available to acquire necessary preclinical evidence to support FDA clearance for the pediatric population.

Delivery of Opioid Antagonists for Ventilatory Emergencies (DOVE)

In collaboration with **AltruMed LLC**, **Jacob Brenner, M.D., Ph.D.** of the University of Pennsylvania is developing the DOVE device. Adolescents remain extremely vulnerable to the adverse effects of opioid use and overdose. The DOVE device is a wearable biosensor that senses and responds to critically low respiratory rate by automatically injecting naloxone and/or alerting first responders, a trusted contact, or a naloxone-equipped bystander. During an overdose, individuals only have a matter of minutes to receive life-saving measures, including naloxone, an opioid overdose antidote. There is an urgent need for novel solutions that passively monitor respiratory drive and trigger automated responses to reverse an overdose when detected. Originally funded through PPDC's early-stage project assistance platform, AltruMed worked with **Archimedic** for prototype development and marketing strategy to advance the technology. In 2022, the group received PPDC direct device funding along with an additional $20,000 of funding to assist with prototype development and FDA clearance.

SeeIV Cover

Nurses at CHOP developed a protective covering to prevent IV infiltrations. The SeeIV is a flexible IV site cover with noiseless closures. In 2015, the PPDC met with the innovators and assisted them with regulatory guidance, commercialization, and functional testing. **MedLine** collaborated with the CHOP innovators and the SeeIV is currently used clinically.

Needle Free Blood Draw (PIVO)

Velano Vascular developed a needle free peripheral blood collection system for pediatric use named PIVO. The PPDC assisted Velano with non-direct funding support in 2015. The PIVO received FDA clearance in 2017, and is currently on the market. Velano Vascular was acquired by Beckton Dickinson in July 2021.

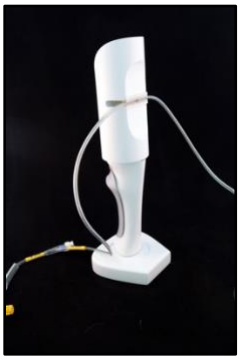
noddle™

Voxello, LLC, of Coralville, Iowa, is developing the noddle™ to address the communication barriers faced by pediatric patients. The noddle™ uses patented technology to detect the smallest intentional gesture and allow patients to access the nurse call system and control a speech generating device. Thus, children who may only be able to produce a tongue click, head nod or other small gesture would be able to summon help and effectively communicate with their caregivers. In 2017, funding was provided by the PPDC to support development and clinical trials of the Voxello technology with hospitalized children, as well as children with developmental disabilities whose barriers to communication may impact their care and medical outcomes. The noddle is currently in clinical use.

OrVac™

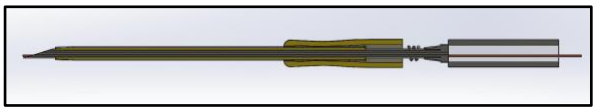
In 2021, **Tychermont Products, LLC**, a woman and minority owned company based in Philadelphia, received PPDC support for the OrVac™, a portable oral aspirator to assist pediatric patients with dysphagia and other swallowing disorders. To date, these patients do not have a way to self-suction oral waste without assistance. The OrVac™ returns control and independence to the patient by providing a portable, non-invasive, and user- controlled device to evacuate oral liquids. At the early stages of the product development, Tychermont Products received assistance through the PPDC's collaboration with **Archimedic** that assists companies with prototype development and marketing strategies. This Class I device has also received $50,000 in additional funding, from institutions such as **Ben Franklin Technology Partners**, for prototype development.

SonoSolve



SonoSolve, a **University of Pennsylvania** spin-off company, is developing a technology that uses high energy ultrasound to clear catheter associated blockages. Using ultrasound energy emitted from a handheld transducer, obstructions can be disrupted and removed without compromising sterility. In 2016, SonoSolve received PPDC nonfinancial support to provide guidance to adapt this technology for pediatrics. They have also received $70,000 in support of prototype development. Of note, the company won the DevelUPmed challenge in 2016.

ThreadRiteIV Catheter



The University of Pittsburgh is developing the ThreadRiteIV Catheter to improve the placement of peripheral intravenous catheters. These catheters are widely used for drug delivery in healthcare, but often require multiple attempts for insertion in children. ThreadRiteIV detects blood vessels through a sophisticated system that measures differences in electrical resistance, and instantaneously alerts the operator of vessel entry via a light, audible, and vibratory signal. This eliminates the dependence on blood return for confirmation of insertion. In addition to the PPDC direct device funding for pediatric development of this device, awarded in 2019, the ThreadRiteIV catheter has also received support from the University of Pittsburgh Center for Medical Innovation, and the Coulter Translational Research Partners II Program. These awards totaled $215,000 and are being used for design finalization and preclinical testing.

Plastic Surgery

InfantEar

A device designed by **TalexMedical, LLC**, founded by **CHOP** plastic surgeon, Scott Bartlett, MD, aims to correct ear deformities in infants. The InfantEar System is a Class I medical device that uses silicon conformers placed along the ear to reshape and correct the deformity over time. It would avoid the need for costly, labor-intensive and painful surgical procedures. Funded by the PPDC in 2016, the InfantEar is currently in clinical use.

CMF Distractor

Ostiio LLC of Philadelphia is developing a novel device for distraction osteogenesis (DO) within the cranio-maxillofacial skeleton. For many years, DO has been used to correct congenital skeletal defects by promoting the growth of new bone. Unlike current DO methods, the Ostiio device would be fully internalized and remote-controlled, thereby decreasing the risk of infection, and improving patient and surgeon satisfaction. Ostiio received PPDC direct device funding in 2018. In addition, they also received funding from Penn Health-Tech, the Wharton Innovation Fund and the NSF. The company is currently pursuing clinical trials.

Pulmonary

Neo™

Dymedso Inc. of Montreal, Canada, is developing the Neo™, a non-percussive acoustic airway clearance device specifically designed for infants and young children with lung diseases such as cystic fibrosis.
The Neo™ uses sound waves for chest physiotherapy, which is more appropriate for toddlers and infants than clapping or percussive treatment. Dymedso received PPDC direct device funding in 2018 and is currently manufacturing their device for the pediatric patient population. In 2020, the Neo was used in clinical trials related to assessing how the device can be used to effectively administer respiratory care in COVID-19 patients.

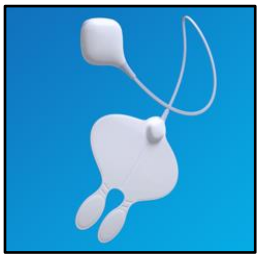
Surgery

Go Scope

X-Biomedical is a Pennsylvania company, based on technology from CHOP based innovators, that has developed and marketed the Go Scope. The Go Scope is an all-inclusive portable/compact digital surgical visualization system. The device offers sharp stereoscopic imaging up to 20x magnification. In 2014, the PPDC assisted the X-Biomedical team by arranging meetings with X-Biomedical innovators, CHOP Technology Transfer, and relevant clinicians. The PPDC also facilitated networking opportunities with individuals from the Wharton School of Business at the University of Pennsylvania. In 2017, the project received $35,000 in funding for prototype development. It has since acquired over $1.4 million of additional funding, and the device is currently being marketed to the dental industry.

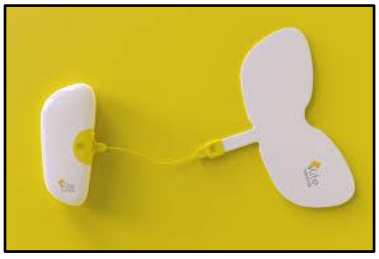
Urology

Soluu™



Global Continence, Inc. of Atlanta, GA is currently in the process of manufacturing Soluu™, a bedwetting mitigation device. Nocturnal enuresis, or bedwetting, affects 200 million children globally and can impact a child's self-esteem and behavior. The device will sense moisture and immediately activate a painless neuromodulation system to prevent bedwetting and alert the child and/or parents. The device, the first of its kind, can be used in children of all ages and is expected to prevent the need for long-term treatment of bedwetting. In addition to direct PPDC funding, received in 2022, Global Continence Inc. raised an additional $200,000 to assist in the manufacturing of the Soluu™ device.

Device to Detect Vesicoureteral Reflux



Kite Medical of Galway, Ireland, is a woman owned and led company developing a device to detect vesicoureteral reflux (VUR) in children. VUR is a condition that can potentially lead to kidney damage. Current diagnostic procedures require catheterization and radiation exposure. This device could offer a noninvasive, child-friendly alternative. Kite Medical received PPDC direct device funding in 2018. Follow-up funding, from sources such as Enterprise Ireland, angel investors, Summit Bridge Capital, and the European Innovation Council contributed to over $2,539,300 in funding to support clinical trials. Kite has also received additional funding totaling over $1,816,000.