Children's National

2023 Innovation Day & Showcase

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Overview +Welcome

Welcome to the inaugural Children's National Hospital Innovation Day & Showcase!

At Children's National, we define "innovation" as the process of translating novelties and discoveries to serve our patients and families, and ultimately, the larger market. With this thesis in mind, our focus is to address the pediatric market's unmet needs for regulated medical products in the categories of (1) drugs/biologics, (2) devices/ diagnostics, and (3) digital health.

We source and scout innovation from the following groups: (1) research-based – discoveries in our research labs, (2) hospital-based – novelties that result from solving unmet needs defined by our clinicians, and (3) external – when we embrace and import pediatric innovation from anywhere in the globe.

Today's presenters are grouped into two categories of (1) pre-tech-transfer research projects, and (2) startup companies. Research projects are interested in forming new collaborations for co-development, sponsored research, and licensing; and startups are interested in new strategic partnerships and raising capital. All presenters will benefit from your valuable feedback, so we thank you for completing a short survey after each presentation. We cannot innovate alone, and we want to partner with you!

Enjoy the Day,

Kolaleh Eskandanian Ph.D., M.B.A.
Vice President and Chief Innovation Officer
Children's National Hospital

AGENDA

10:00 AM	Welcome	
10:15 AM	Keynote Speaker	*Kwame Ulmer*, Managing Director, Medtech Impact Partners
10:30 AM	Robotically-Assisted Ankle Rehabilitation	*Kevin Cleary*
10:45 AM	Bearanchors	*Anthony Sandler*
11:00 AM	Third Generation Sequencing Diagnostics	*Yi-Wen Chen*
11:15 AM	EasyTBSA	*Cindy Colson*
11:30 AM	Break	
11:45 AM	Biliary Tract-Specific Fluorescence Imaging	*Richard Cha*
12:00 PM	Trach Sense	*Jules Sherman*
12:15 PM	Connector Protectors	*Lori Irvin*
12:30 PM	Baby Grow Pro	*Natasha Shur*
12:45 PM	Lunch and Networking	
1:30 PM	Fireside Chat What Researcher and Entrepreneurs Need to Know about IP	*Sally Allain* Luke Pedersen
2.00 PM	CorInnova	*William Altman*
2:15 PM	AlgometRx	*Julia Finkel*
2:30 PM	Bloom Standard	*Annamarie Saarinen*
2:45 PM	CathWear	*Brian Mohika*
3.00 PM	Gabi SmartCare	*Jonathan Baut*
3:15 PM	Break	
3:30 PM	Luminoah	*Neal Piper*
3:45 PM	MiraHeart	*Danielle Gottlieb Sen*
4.00 PM	PediaMetrix	*Reza Seifabadi*
4:15 PM	PeriCor	*Justin Opfermann*
4:30 PM	EzaLife	Tyler Mironuck
4:45 PM	LYO Syringe	*William Meredith*
5:00 PM	Tour of CNRIC + JLABS | Networking	
5:30 PM	Cocktail Reception	
7:00 PM	Adjourn	

Thank you to our sponsor for making this event possible!

TEDCO

LEADING INNOVATION TO MARKET

Research Project Profiles

Home-based robotically-assisted ankle rehabilitation for children with cerebral palsy

Presentation: Robotically-assisted ankle rehabilitation (Kevin Cleary)

IP status: Patent Filed

Background

Children with cerebral pals:y have decreased motor control, most commonly in the leg or legs, that can lead to difficulties with ambulation.

01 Technology Overview

Our home-based system could improve their range of motion at the ankle and lead to them being better able to keep up with their peers.

02. Team members, their specialties, and role in the project

Kevin Cleary
Director of Bioengineering

Reza Seifabadi
Engineering Lead

03. Stage of Development
(pre-clinical, clinical, post-market, etc.)
and what preliminary results are shown

Pre-clinical
https://ieeexplore.ieee.org/abstract/document/8779468

04. Advantages

- Home-based system eliminates need to travel to the hospital for regular PT appointments

Bearanchors

Presentation: Bearanchors (Anthony Sandler)

IP status: Provisional Filed

Background

Device used for dressing and anchoring feeding and drainage tubes in patients

01. Technology Overview

Drainage and feeding tubes inserted in patients are often critical for treatment, recovery and care. These tubes however can be uncomfortable and risk inadvertent removal. The technology developed is a dressing combined with an anchoring device that will allow for comfort, ease of use, avoid tract related complications, prevent inadvertent removal and lower the cost of care.

02. Team members, their specialties, and role in the project

Anthony Sandler
Clinical Lead

Reza Seifabadi
Engineering Lead

03. Stage of Development
(pre-clinical, clinical, post-market, etc.)
and what preliminary results are shown

Clinical
No Preliminary Results

04. Advantages

- A reduction in CLABSI rates by keeping multiple types of lines, tubes and drains separated.
- Other products on the market that aim to address line disconnection do not provide tamper resistance with a novel closure mechanism that allows the lines and tubes to infuse medications or fluids while in
- Economical Solution

Third Generation Sequencing Diagnostics

Presentation: Third Generation Sequencing Diagnostics (Yli-Wen Chen)

IP status: Patent Filed

Background

Molecular diagnosis of facioscapulohumeral muscular dystrophy has been challenging due to the large size of the repeat sequences (D4Z4 macrosatellite repeats). The approach here will allow fast and accurate molecular diagnosis of FSHD and other genetic disorders in a cost-effec

01. Technology Overview

Nanopore long-read sequencing with CRISPR/Cas9 enrichment is used to target the genomic region(s) of interest. The data can be used to determine nucleotide sequences as well as DNA methylation of the same molecule. This is the only technology allow this type of analyses, which is critical for inherited diseases that have both genomic and epigenomic components.

02. Team members, their specialties, and role in the project

Yi-Wen Chen
Principal Investigor

Alexander Liu
Experimental design and Bioinformatics

Nick Settas
Assay development

03. Stage of Development (pre-clinical, clinical, post-market, etc.) and what preliminary results are shown

Clinical
Manuscript in preparation

04. Advantages

- This is the only technology that can sequence the whole repeat array and determine DNA methylation at the same time.

EASYTBSA

Presentation: EASYTBSA (Cindy Colson)

IP status: Patent Filed

Background

Current methods of burn estimation can lead to incorrect estimates of the total body surface area burned, especially among injured children. Inaccurate estimation of burn size can impact initial management, including unnecessary transfer to burn centers and fluid overload during resuscitation. To address these challenges, we developed a smartphone application (EasyTBSA) that calculates the total body surface area of a burn using a body-part by body-part approach. The aims of this study were to assess the accuracy of the EasyTBSA application and compare its performance to three established methods of burn size estimation (Lund-Browder Chart, Rule of Nines, Rule of Palms).

01. Technology Overview

Smartphone application (EasyTBSA) that calculates the TBSA of a burn using a body-part by body-part approach.

02. Team members, their specialties, and role in the project

Cindy Colson
Project Lead

Randall Burd
Project Oversight, Study Design, Author

Kevin Cleary
Project oversight, access to mwebware for initial app development

Tyler Salvador
3D scanning and calculations

Hadi Fooladi
applications updates

Rima Izem
Statistical Plan

03. Stage of Development (pre-clinical, clinical, post-market, etc.) and what preliminary results are shown

Clinical

Results - https://doi.org/10.1136/emermed-2022-212308

04. Advantages

- Small cDNA for this gene therapy allows packaging using a single AAV.
- Use of liver targeting avoids the challenges for body wide muscle delivery of AAV
- No detectable toxicity

Biliary Tract-Specifc Fluorescence Image-Guided Surgery

Presentation: Biliary Tract-Specific Fluorescence Imaging (Richard Cha)

IP status: Patent Filed

Background:

More than 40,000 new cases of liver cancer are diagnosed each year, causing more than 30,000 deaths in the U.S. alone. Gallbladder disease is also one of the most common conditions in the U.S., with more than 20 million people affected annually. Procedures to treat these diseases have many challenges. During minimally invasive surgery, including laparoscopic cholecystectomy or robot-assisted hepatectomy, surgeons can struggle to precisely identify the bile ducts because of a narrow field of view or because they are embedded in fat or other tissues. Existing FDA-approved contrast agents that can enhance the biliary anatomy such as indocyanine green (ICG) aren't well tailored for HPB surgeries because of the timing of their administration and their inferior ability to highlight biliary structures. In addition, while pre-operative imaging has improved outcomes, it cannot be used to predict leaks from the surgery itself.

01. Technology Overview

Researchers at Children's National Hospital and the National Cancer Institute (NCI) have developed a novel, near - infrared dye that can help surgeons identify biliary structures and detect bile leakage during liver surgery, offering a promising tool that may someday improve outcomes for patients undergoing gastroenterology procedures.'

02. Team members, their specialties, and role in the project

Dr.Richard Cha
Project Lead

Dr. Benjamin Philosophe

MD -- Hepatobiliary & Liver Transplantation Surgery, Clinical Advisor

Dr. Michael Bouvet

MD -- Surgical Oncology, Clinical Advisor

Dr. Martin Schnermann

PhD -- Organic Chemistry, Collaborator

Dr. Anthony Sandler

MD -- General and Pediatric Surgery, Clinical Advisor

03. Stage of Development

(pre-clinical, clinical, post-market, etc.)

and what preliminary results are shown

Pre-clinical.

https://onlinelibrary.wiley.com/doi/10.1002/lsm.23661

04. Advanatges

- Several promising advantages over existing surgical tools during non-clinical testing.
- When administered into the liver, dye was excreted and visible in bile ducts within minutes, without significant or prolonged impact on organ tissue
- Superior view of leaks

Trach Sense

Presentation: Trach Sense (Jules Sherman)

IP status: Provisional Filed

Background

In the United States, more than 100,000 tracheostomies are performed annually with 4,000 of them being performed in children. Of these tracheostomy procedures, it is expected there to be a complication rate of 3.2%, with many of these catastrophic events, including death. Pediatric tracheostomy is a life-saving procedure for children with severe respiratory compromise or upper-airway obstruction. Recently, Tracheostomies in children have increased. . Children with medical complexity (CMC) who have undergone a tracheostomy represent a complex cohort of patients who have a sustained reliance on medical technology for long-term survival. By investing in more advanced remote healthcare technology for children with trachs, healthcare providers can ensure that follow-up appointments are more accessible to patients, while also making it easier for caregivers at home to monitor a child's breathing.

01. Technology Overview

Our improved tracheostomy tube incorporates a disposable remote CO2 sensing technology, which detects the levels of CO2 in exhaled air. This technology will eventually enable home caretakers or in-hospital clinicians to receive continuous data regarding the patient's respiratory function via a mobile app.

02. Team members, their specialties,and role in the project

Jules Sherman
MFA, Product Design

Dr. Habib Zalzal
Clinical Champion

Dr. Ghee Ong
University of Oregon Faculty, Electrical Engineering

Kaylee Meyers
Ph.D. Student, U of O Electrical Engineering

Ethan Cooper, Noah Jagdman, Aqeel Muthaliff, Shahmeel Naseem,
MD Bioengineering Students

03. Stage of Development
(pre-clinical, clinical, post-market, etc.)
and what preliminary results are shown

Pre-Clinical
Excellent experimentation used to find results

04. Advantages

- No trach products on the market that has a disposable built-in CO2 sensor that confirms proper placement and continuously monitors breathing by connecting to a mobile application for hospital nurses and home caretaker

Baby Grow Pro

Presentation: Baby Grow Pro

IP status: Provisional Patent

Background

Routine Growth Screening Improvements

01. Technology Overview

Our home-based system could improve their range of motion at the ankle and lead to them being better able to keep up with their peers.

02. Team members, their specialties, and role in the project

Natasha Shur, MD
Project Lead

03. Stage of Development
(pre-clinical, clinical, post-market, etc.)
and what preliminary results are shown

Pre-Clinical
1) Survey of 58 providers 2) Currently evaluating the concept in clinic

04. Advantages

- Educates and teaches about infant growth, earlier detection, chance to catch errors

Connector Protectors: A Solution to Medical Line Disconnection

Presentation: Connector Protectors (Lori Irvin)

IP status: Patent Filed

Background

Intravenous catheter use and feeding tubes are used to manage and treat a multitude of conditions and disease processes. Pediatric and adult patients experience disconnection of their medical lines, tubes and drains for various reasons. Connector Protectors provide tamper resistance to the connections points with a novel closure mechanism. We are scheduled to begin our IRB approved study in May 2023 to test the feasibility and acceptability of nurses using these devices on in-patient units at Children's National Hospital.

01. Technology Overview

Connectors Protectors have a novel closure mechanism that fits over IV and feeding tube connection points. They require a higher level of dexterity and intuitive knowledge to open. A trained adult can open the device with ease.

02. Team members, their specialties, and role in the project

Lori Irvin
Project Lead

Jules Sherman
MFA Co-inventor

Laura Nicholson
MSN, RN, CPN MHSE, Principal Investigator

Kevin Cleary
Project oversight, access to mwebware for initial app development

Francesca Joseph
MD, (PI Proxy)

Yama Thakkar
Clinical Research Coordinator

03. Stage of Development
(pre-clinical, clinical, post-market, etc.)
and what preliminary results are shown

Pre-Clinical
Results - Preliminary survey showed that nearly 85% of nurses reported that disconnection occurs at least 25% of their patient care time

04. Advantages

- Patient Safety

Company Profiles

AlgometRx: Bringing Objectivity and Precision to Pain Management

www.algometrx.com

Presentation: Algometrx

IP Status: 3 Issued Patents, 2 Pending Patents

Reference:
US 9326725 [B2], US 9980642 [B2],
US 10555687 [B2], US 2021/0045679 [A1],
US 2021/0045680 [A1]

AlgometRx has developed a novel pluripotent technology to allow the objective treatment of pain. The current standard of care for the assessment of pain and inflammation uses subjective scales like the Visual Analog Scale. This approach is mechanism agnostic and fails to classify the etiology of the insult or help guide a specific intervention. Pain is often treated empirically, with drugs being used in a trial-and-error fashion leading to lack of efficacy, increased healthcare costs, unnecessary side effects, tolerance, and abuse—all pointing to the need for more objective assessment and better monitoring of the impact of analgesics. The AlgometRx Nociometer® is a patented technology that determines pain type and intensity, as well as the suitability of an analgesic intervention. This enables a fundamental paradigm shift in pain assessment and analgesic prescribing/monitoring. Our initial applications of this technology include for the assessment and monitoring of Lupus, Chemotherapy Induced Peripheral Neuropathy (CIPN), Fibromyalgia, Rheumatoid Arthritis and other pain or inflammatory conditions. The AlgometRx technology platform detects, characterizes, evaluates, and monitors pain and inflammation and the appropriateness of an intervention

Technology Overview

The AlgometRx Nociometer is a novel integration of infrared pupillometry and neuroselective neurostimulation. The technology leverages the discovery by Dr. Finkel and her team that a non-painful neuroselective stimulus evokes a pupil response that can be quantified and used to characterize pain type and intensity. The AlgometRx Nociometer uses innocuous neuroselective stimulation to evoke a pupillary dilation (nPRD) for each nerve type which is used to characterize nociceptive processing that occurs during pain. Nociception, the neural process of encoding and processing noxious stimuli, is the first step of the complex physiological process which ultimately leads to experience of pain and is a component of pain that is the target of analgesic pharmacological and non-pharmacological treatments.

Stage of Development and what the results are showing

Since the inception of AlgometRx in 2015, significant strides have been made in the development and understanding of this revolutionary technology. Initial pilot data collected at CNH demonstrated the ability of this technology to characterize and differentiate pain types (e.g. nociceptive vs neuropathic). Subsequent studies have shown the utility of this technology across a number of pain populations. The overall pain market consists of a large number of unique pain conditions and is therefore highly segmented. In addition to expanding the potential applications of this technology, efforts have been made to improve and enhance the technology itself. Expanding upon the initial prototype developed in 2018, AlgometRx has contracted medical device development firms to assess the existing technology and identify the steps necessary to develop an FDA ready version of the technology.

Company Milestones

- Awarded Phase I SBIR from National Institute on Drug Abuse for initial investigation of application of device to pain and the opioid crisis
- Developed eight AlgometRx research prototypes and conducted proof-of-concept observational pain/analgesic assessment studies
- Winner of via FDA Innovation Challenge; selected out of a pool of 250+ applicants
- Selected for MedTech Innovator 2020 Pediatric Accelerator
- Winner of Quickfire Challenge and selected as initial member of JLABS Washington, DC
- Awarded Phase I SBIR from National Cancer Institute for development of VIPN application
- Awarded Phase I SBIR from National Institute of Arthritis and Musculoskeletal and Skin Diseases for development of Lupus application
- Winner of J&J Innovation Quickfire Challenge to evaluate the application of this technology to the assessment Immunotherapy Neurotoxicity

Team Members and Their Roles

Julia Finkel, M.D, Scientific Advisor

Kevin Jackson,Chief Operating Officer

David Gross, MSEE, Chairman + Interim Ceo

David Heller, MBA, Investor

Susan Alpert, PhD, MD, Regulatory Consultant

AusculTech Dx : Enabling smart auscultation through artificial intelligence

IP Status: 2 Issued patents
Reference: US 10,251,562. 2019, US 11,484,283. 2022 Nov 1.

auscultechdx.com

Presentation: AusculTech Dx

AusculTech Dx is a digital health startup that spun off from Children's National Hospital to commercialize a smart auscultation technology with pediatrics focus. AusculTech Dx is a young, vibrant organization that strives to bring novel, intuitive, and cost saving technology to pediatric medicine. The startup has been founded by the inventors of the technology: Raj Shekhar, PhD and Robin Doroshow, MD. Dr. Shekhar has translated novel technologies from research lab to FDA-cleared products. Supported through two Phase I and one Phase II STTR awards, AusculTech Dx is active in developing a digital auscultation platform with machine learning algorithms for various pediatric cardiopulmonary conditions.

Technology Overview

We have developed a complete smart auscultation platform that includes a novel wireless stethoscope, a custom mobile app with embedded artificial intelligence algorithms, and a web-based application portal. Our focus on pediatric conditions (heart murmurs, pediatric asthma) affecting large number of children makes us unique. The platform further supports telehealth. Our platform is also scalable and can be extended to most clinical conditions, adult or pediatric.

Stage of Development and what the results are showing

Pre-clinical with clinically deployed advanced prototype. The results are showing readiness to go for regulatory clearances and early stage commercialization.

Company Milestones

- Premarket clearances for hardware and software algorithms,
- Setting up product manufacturing and pilot production
- Scientific publications on developed AI algorithms.

Team Members and Their Roles

Raj Shekhar, PhD, CEO & CTO, Serial medtech innovator, Experience with commercializing academic research
Mark Chandler, MBA, Executive Chairman, Early-stage technology commercialization and IP expert
Robin Doroshow, MD, CMO, Pediatric cardiologist with 35 year experience
Shilpa Patel, MD, CMO, Emergency medicine physician with pediatric asthma expertise.
Youness Arjoune, PhD, Director of Engineering, Manage R&D of the product

Bloom Standard: Saving Lives with Self-Driving Rapid Ultrasound Screening for Babies & Children

IP Status: 1 Patent Pending
Reference:: 15/416,634

bloomstandard.com

Presentation: Bloom Standard:

Bloom Standard develops technologies to support earlier detection and equitable access to care for babies and children with critical medical conditions. Bloom's rapid pediatric automated ultrasound technology is a clinical decision support tool for ultrasound/echo screening in front line (primary care), remote and resource-constrained settings.

Technology Overview

The hardware is built around a chip-based core imaging technology that reduces development costs over traditional electric crystal imaging devices, while providing programmable beam steering capabilities that are well suited for tiny patients. The software algorithms are being developed and optimized using convoluted neural network (CNN) models focused on specific cardiac and lung training sets in newborn and infant patients. The software recognizes key ultrasound data matched against baseline norms to flag abnormal presentations based on structure, flow, and features.

Stage of Development and what the results are showing

Bloom's ultrasound is at TRL 6-7, in clinical feasibility trials for hardware, early preclinical on software (machine learning applications). Key findings: Sensors produce data comparable in resolution + quality to FDA cleared commercial pediatric probes, above expected flexibility in range, depth and frequency (for smaller patient populations); capability to "place and scan" achieved, utilizing key targeted windows into neonatal heart and lung; feasible to switch depth, frequency and electrical inputs through chip programming, allowing phased array and sweeps needed to capture ultrasound data without changing probes to accommodate patient sizes or pathologies. Upcoming: testing of smaller housing, "vest" wrap for improved patient and user experience, interoperability of ultrasound data (raw + processed) utilizing cloud-based infrastructure. First two phases of external product safety testing completed.

Company Milestones

- Clinical Data Collection (100+ patients with V3 prototypes completed) at Mexico clinical sites, on track for additional 200 patients in Q2 —-> Onboarding and inservice training for added sites scheduled for May 2023.
- Fundraising: Pre-seed oversubscribed, closing Jun 1. In due diligence with 4 funds for 2023 seed round). Seed pipeline at 18 VC and impact investor groups.
- Regulatory: Initialized regulatory consultancy and QMS services with Denver-based ERI Group, finalization of FDA submission strategy and timeline for separate hardware and software submissions.
- New Clinical Partnerships: Texas Children's Hospital, Hospital del Nino DIF, Hidalgo (MX), Hospital Infantil de Mexico Federico Gomez (Mexico City), Prince of Wales Hospital.
- Product Dev: V4 Prototyping batches in production, sensors secured, accelerating ML algorithm development, heart and lung parameters (with Q1 prospective datasets), two new patents in development for filing in Q2.
- Participated in WHO Global Quality Grand Rounds, highlighting collaborative screening work in Mexico | Bolivia.
- Texas Medical Center (TMCi) cohort (program is near completion w potential for $500K follow on investment.
- TUV SUD safety testing for electrical, biomedical materials and output safety, phase 3 report issued.
- Software/ML: accelerating algorithm development, heart and lung parameters (with Q1 prospective datasets).
- 4 separate non-dilutive grant submissions in process (Q2 2023).
- Accelerate UK (EU-funded) program completed, NHS ethics review submitted; Continued NHS collaborations for clinical, technical support from Swansea Uni / Accelerate partners for UK clinical pilot, regulatory submission framework.

Team Members and Their Roles

Annamarie Saarinen, CEO
Jacob Colvin, COO
Lewis McFadyen, CTO
Joey Worlidge, CRO
Maria Victorova, PhD; Research + Robotics
Oscar San Roman, MD, MPH, Global Health
Alyssa Abo, MD, MBA, Clinical Advisor
Amr El-Bokl, MD, MPH, Clinical Advisor
Ben Knight-Gregson, CEng, PhD

CathWear: Improves privacy during treatment and recovery

IP Status: 2 Issued US Patents
Reference: US Patents 8486035, D 981,079

cathwear.com

Presentation: CathWear

Class I Medical Device

Technology Overview

A medical underwear designed for post-surgical patients wearing a leg bag, with a breathable material and machine wash/ dry product to improve procedure outcome.

Stage of Development and what the results are showing

Fully marketed product with online sales

Company Milestones

- Only product in our category invented by a nurse, and covered by Medicare.
- #1 product Online (Amazon and Google) as evidenced by reviews and ratings in comparison to the nearest competitor.
- Being tested for pediatric use

Team Members and Their Roles

Brian Mohika, RN, CEO

Gabi SmartCare : Leveraging pediatric care to improve lifelong health worldwide

IP Status: 3 Patents Pending
Reference: Upon Request

www.gabismartcare.com

Presentation: Gabi SmartCare

Gabi SmartCare is a digital health company dedicated to revolutionising pediatric care delivery. We focus on empowering parents with the right tools and resources to provide timely and personalized care, making a meaningful difference in the lives of millions of families globally.

Technology Overview

Pediarity(TM) by Gabi SmartCare is the 1st end-to-end solution, from monitoring to data-driven medical support, exclusively dedicated to pediatrics, bringing peace of mind to parents while reducing unnecessary emergency visits and preventable hospital admissions. Pediarity(TM) includes: - a Miniaturized medical wearable monitoring the main vital signs of the children from 0 to 12 years old - a Health analytic platform converting the million data points into an actionnable health report dedicated to physicians - a Medical team accessible 24/7 by patients to support primary care and triage

Stage of Development and what the results are showing

- FDA clearance pending: 510(k) submitted
- Higher accuracy than in hospital tools of HR, SpO2 and Respiratory Rate on dark skins (great accuracy on all type of skins)
- 93% of the parents who used the solution felt reassured
- 99% of the parents who used the solution felt it easy to use
- 96% of adoption from physicians: they are willing to prescribe the solution to 96% of the enrolled pat

Company Milestones

- Pre-Seed: turn prototype into a first product (GSC 1)
- Seed: Test and iterate GSC 1 through sales (for research) and self-sponsored studies.
- Eventually turned GSC1 into PediarityTM v1, our 1st (soon) FDA cleared soared solution

Team Members and Their Roles

Steven Coughlin, Market and clinical expert
Nikki Lindgren, Marketing expert
Raz Dan, Hardware and supply chain expert
Saba Hacq, CMO and Virtual Care team development expert
Olivier Staquet, CTO
Edouard Carton, Co-founder and COO
Jonathan Baut, Co-founder and CEO
David Kalfa, MD, head of pediatric cardiac surgery at Columbia Irving Medical Center
Brigitte Fauroux, Pr, head of respiratory at Necker in Paris
Lori A. EricksonPhD, RN, MSN, CPNP-PCDirector, Remote Health Solution at children Mercy
Shireen Atabaki - MD, PhD, MphMedical Director
Telemedicine ED, Prof. Pediatrics Health System at Children's National
Francesca Joseph, MD, Pediatrician at Children's National and FDA consultant pediatric devi

Luminoah: Reinventing Tube Feeding

IP Status: 8 Patents
Reference: Upon Request

luminoah.com

Presentation: Luminoah

Luminoah is a MedTech company that aims to disrupt the enteral feeding market by offering a wearable device, daily consumable, and digital health platform that enables patients to manage their nutritional status and eliminate the need for an IV pole.

Technology Overview

Luminoah is developing a wearable device, daily consumable, and digital health platform with the aim to improve the quality of life for enteral nutrition patients and decrease the readmission due to malnutrition.

Stage of Development and what the results are showing

We have a working device that can deliver enteral nutrition at a controlled rate and daily disposable. We are nearing design freeze and will submit a 510k to the FDA later this year.

Company Milestones

- Working device
- May 2023 - Closing on a $6m Series A
- 8 patents submitted

Team Members and Their Roles

Neal Piper, Founder & CEO
Brian Bergeron, President & COO Hill
Johnson, Product Lead
Landon Gilkey, Hardware Engineer
Kevin Owens, Electrical Engineer
Marty Weiner, Software Lead
Andy Dehennis, Systems Engineer

MiraHeart: Giving vulnerable children at risk of CHF the care they deserve from the comfort of their own home.

IP Status: Invention Disclosure Submitted

cbid.bme.jhu.edu

Presentation: MiraHeart

MiraHeart is a company made up of a group of graduate students at Johns Hopkins Center for Bioengineering Innovation and Design and clinicians at Johns Hopkins School of Medicine. MiraHeart's mission is to improve the lives of some of the most vulnerable members of our society - children with heart defects at risk of developing congestive heart failure (CHF). Every year in the United States, 35,000 children are affected by CHF, a disease with a 6.3% mortality rate1,2. Unfortunately, there are currently no remote monitoring tools available, leaving families with no objective way to track their child's CHF progression at home. Lack of monitoring leads to CHF progression, where hospitalization and more intensive treatments are necessary, resulting in higher treatment costs and more pain for the child. MiraHeart addresses this gap in care. Our wearable, non-invasive device provides objective metrics of CHF by reading the child's central venous pressure (CVP) and transmitting this directly to physicians. Our device aims to empower patients and physicians with early and accurate monitoring of CHF, ultimately providing the care and support these children desperately need. Our passion for improving the lives of children drives us, and we are committed to positively impacting the lives of those affected by CHF by allowing for decreased lengths of stay and rates of hospitalizations.

Technology Overview

MiraHeart consists of a small, optical sensor array and software system harbored in a small electronic parcel that utilizes hydrogel adhesive patches secured on the child and worn twice daily, for 5 minutes each. CVP is a metric that can change based on activity level; therefore, in children, it is essential to take measurements when the child is most calm, in the morning and at night. MiraHeart is prescribed by the patient's cardiologist and utilized by the child's caretaker. The device uses a proprietary localizing algorithm to optimally measure the sensors that are on the target physiology. The optical sensors emit light onto the target physiology and measure the intensity of light reflected. This data is then analyzed to obtain a proprietary hemodynamic parameter that can be correlated to CVP measurements and transmitted directly to the cardiologist. With this information, MiraHeart facilitates proper decision-making on CHF medications, transforming care with a small shift in the day-to-day workflow of clinicians and families.

Stage of Development and what the results are showing

Thus far, we have prototyped a first iteration prototype and performed feasibility testing. The results of the accuracy and precision of the proprietary hemodynamic parameter between adult patients reveals high precision to acceptable physiologic. ranges. Next steps in development involves building a correlation of the hemodynamic parameter to catheter-based measurements of CVP. Our team submitted porcine and pediatric human protocols to study this across age ranges. Our clinical developmental study in the pediatric intensive care unit has been approved by the Institutional Review Board (IRB), and with recruitment underway, it will be completed in November 2023.

Company Milestones

- June 2022 - Core Founding Team
- September 2022 - Clinical and Technical Advisory Board Created
- January 2023 - First Iteration Prototype Created
- March 2023 - Regulatory Strategy Confirmed by Consultation by Hogen Lovells
- April 2023 - Non-Dilutive Fundraising Started
- May 2023 - First Clinical Study in Johns Hopkins Approved & Started

Team Members and Their Roles

Saisamhitha (Sam) Dasari, Co-Founder

Bhavya Gopinath, Co-Founder

Carter Gaulke, Co-Founder

Sunny Patel, Co-Founder

Dr.Danielle Gottlieb Sen, Co-Founder

PediaMetrix Inc: Transforming pediatric healthcare through AI and computer vision

IP Status: Patent Pending
Reference: 20210004957

PEDIAMETRIX.COM

Presentation: PediaMetrix

We are Ph.D. scientists from Johns Hopkins, Oxford, and NIH who became entrepreneurs after our son's experience. We are building a Computer Vision/AI platform to protect children from numerous health problems. Our beachhead solution is the first and only FDA-cleared mobile app for infant cranial evaluation for parents and primary care physicians for early detection and referral of a variety of skull conditions. Early customers have already performed over 1,000 scans. Our patented technology will be applied to adjacent body deformity conditions including ear, dental, and spine deformities for point-of-care early diagnosis and referral to specialists touching the lives of 40M children.

Technology Overview

Late skull deformity detection results in intensive and expensive treatment options. Currently, there is no objective measurement tool in pediatric offices. We bring the power of a specialists to the point of care using a smartphone AI and computer vision. Same patented technologies will be applied to other body deformity conditions such as spine, dental, and ear deformities for point-of-care detection and early referral.

Stage of Development and what the results are showing

FDA-cleared - early revenue from MVP.

Company Milestones

- Develop SoftSpot3D (adding new indications, expanding to other conditions)
- Make a strong sales and marketing team
- Outside of the US sales and marketing

Team Members and Their Roles

Freya Aalamifar, PhD: founder & CEO Reza

Seifabadi, PhD, co-founder & COO

Marius Linguraru, co-founder and CIO

PeriCor LLC : Eliminating open chest surgeries in newborns and infants.

pericorllc.com

Presentation: PeriCor LLC

IP Status: 2 Utility Patents, 1 Provisional Pending

Reference:
US 10925474[B2]; US WO2015123700[A1]; US 11337726 [B2]; US WO20190064A1

PeriCor, LLC is a cardiac medical device company developing surgical tools and techniques that provide safe and effective treatment for the vulnerable pediatric population. Their flagship product, PeriPath, enables safe pericardial access under direct visualization for the implantation of pacing leads and ablation therapies. Initially formed in collaboration between engineers and doctors within the Sheikh Zayed Institute for Pediatric Surgical Innovation, PeriCor, LLC spun out from Children's National Health System in 2016 and has received over $2.5M USD in funding through philanthropic, NIH, and industry-sponsored awards.

Technology Overview

PeriCor's focus is the development and commercialization of PeriPath; a thoracic access port that converts open chest heart surgery to a minimally invasive procedure. Infants and small children that need pacing or defibrillation therapy require an open chest surgery to suture the pacing leads to the outer surface of the heart. With the PeriPath port, an electrophysiologist can implant pacemaker and defibrillator leads on the epicardium of the heart through a minimally invasive 1cm incision. Pericardial access and device implantation is visualized by a thoracoscope to avoid injury to cardiac structures and confirm device fixation without the need for fluoroscopy. This technique results in shorter surgical times, quicker recoveries, and less pain for the patient. PeriPath is compatible with any therapy smaller than 8mm in diameter including pacemaker leads, defibrillation leads, ablation catheters, and miniature pacemakers.

Stage of Development and what the results are showing

PeriPath has completed preliminary bench testing, Simulated verification, and validation testing, GLP preclinical testing, and demonstrated compatibility with commercial pacemaker leads, defibrillation leads, miniature pacemakers, and ablation catheters. The product has completed design for manufacturing testing, failure modes and effects analysis, and usability testing. Two presubmission meetings with the FDA confirmed a 510(k) regulatory pathway with appropriate predicate device and acceptable testing plan. In Q3 of 2023, the first production PeriPath devices will be submitted for verification and validation testing, followed by a 510(k) submission in Q4. Our company has published over 10 peer reviewed manuscripts demonstrating the usability, safety, and effectiveness of the device in pediatric sized preclinical models.

Company Milestones

- 2016 - PeriCor, LLC is founded
- 2016 - Awarded funding from the National Capital Consortium's sponsored Pediatric Device Innovation Competition.
- 2016 – Finalist for the Design of Medical Devices 3-in-5 contest
- 2017 - Completed first FDA presubmission confirming a 510(k) regulatory pathway with appropriate predicate device and animal model
- 2017 – Secured philanthropic funding for landmark GLP animal studies comparing PeriPath implantations to the open surgical standard of care.
- 2017 – Finalist in the MedTech Innovator Showcase at Advamed.
- 2018 – Secured Medtronic sponsored funding to conduct pacing studies using PeriPath to implant the Micra pacemaker in an infant porcine model.
- 2018 – Awarded Phase I SBIR funding from the NIH to conduct pivotal preclinical studies demonstrating compatibility of the device in patients with previous thoracic surgeries.
- 2019 – Conducted a supplemental presubmission meeting with the FDA to confirm verification and validation testing plans for a regulatory submission.
- 2020 – Awarded funding from the Philadelphia Pediatric Medical Device Consortium to conduct design for manufacturability testing.
- 2021 – Awarded Medtronic sponsored funding to demonstrate compatibility of the PeriPath device with epicardial pacing leads.
- 2022 – Awarded Phase II SBIR funding from the NIH for complete verification and validation testing, obtain regulatory approval, and conduct first in human clinical trials.

Team Members and Their Roles

Charles Berul, MD, Co-Founder,CEO
Justin Opfermann, MS, Co-Founder, CTO
Bradley Clark, MD, Co-Founder,CMO
Axel Krieger, PhD, Co-Founder, Technical Adviser
Rohan Kumthekar, MD, Partner, Clinical Advisor
Mark Chandler, MBA, Business Advisor

3 Cord Management Group: Solving problems and answering needs through novel device innovation

IP Status: Patent Pending

Presentation: LYO Syringe (John Meredith)

3 Cord Management Corporation is a privately held, for-profit holding company that focuses on the development and commercialization of new innovative devices that are currently aimed at answering various modern healthcare needs.

Technology Overview

We will be presenting an overview of our novel dual-chamber syringe that will ultimately be used for the single-dose storage, reconstitution and delivery of lyophilized drug and biologic products

Stage of Development and what the results are showing

Working proof-of-concept prototypes have been developed. A non-binding meeting with the FDA provided invaluable feedback and encouragement. We were told that our technology is both "transformational and disruptive".

Company Milestones

- Early 2021 (as the Covid 19 pandemic took hold) - Initial concept born in response to the need for a simple and economical single-use lyophilized vaccine delivery device.
- Spring 2021 - Initial working prototypes proved that preliminary design concepts will definitely work.
- Summer 2021 - Refined working prototypes developed and duplicated.
- July and November 2021 - Provisional Patents filed.
- December 2021 - Briefed the Children's National Innovation Ventures Team.
- February 2022: Formal (virtual) presentation to the National Children's Consortium for Pediatric Device Innovation (NCC-PDI)
- March 2022 - US FDA non-binding PCI Briefing.
- July 18, 2022 - Regular Patent Application No. 17/867,636 FILED.
- 2022 – 2023 - Commercialization Team Building and Market Research continues.
- January 19, 2023 - Regular Patent Application No. 17/867,636 PUB

Team Members and Their Roles

William R. Patent, Inventor, Holder/Applicant and Joint Owner

Anita J. Meredith, Inventor, Holder/Applicant and Joint Owner

CorInnova, Inc.: Leveraging pediatric care to improve lifelong health worldwide

corinnova.com

Presentation: CorInnova, Inc

IP Status: 16 US patents issued, 4 US patents pending, 16 International Issued/Allowed

Reference:
7,445,593; 8,187,160; 7,935,045; 7,871,366; 8,545,387; 9,642,957; 10,398,556; 8,944,986; 9,259,520; 8.550,976; 9,510,746; 11.511,102; 17/861,581 Pending; 9,833,551; 9,388,318; 10,463,496; 10,507,271; 17/765,661 Pending; 15/692,345 Pending; 17/395,052 Pending

CorInnova is developing a cardiac medical device that is non-blood contacting, biventricular and pneumatically driven. The device provides gentle direct cardiac compression for temporary mechanical circulatory support that avoids the many adverse events caused by the blood contact inherent in existing devices.

Technology Overview

We use capacitive sensing to non-invasively capture pulse waveform data that is wirelessly streamed to mobile devices where accurate blood pressure values are derived through the use of machine-learning algorithms and displayed in real-time. Our devices are comfortable to wear and easy to use. They have been extensively tested on patients ranging from premature infants as small as 0.5 kg to 98-year old seniors.

Stage of Development and what the results are showing

CorInnova has completed preclinical studies and is preparing for first-in-human pilot studies in 12 to 18 months. Preclinical work included 14-day studies in a model of chronic heart failure, demonstrating safety and efficacy. The results demonstrated improved left ventricular ejection fraction, heart recovery and enhanced survival. Excellent safety compared to current devices was demonstrated - there was no bleeding, no thrombosis, no stroke or neurologic events, no infection, no blood damage, no malignant arrythmias (ventricular tachycardia, ventricular fibrillation, atrial fibrillation). CorInnova has successfully developed a pediatric prototype of its non-blood contacting biventricular cardiac assist system and completed a preclinical pilot test. The pediatric prototype was successfully tested in vivo to observe the effects of heart assist on a small, acutely depressed ovine heart. Following a successful minimally invasive deployment of the prototype, activation of the system resulted in an improvement in various hemodynamic parameters, including between 85-95% recovery of baseline stroke volume (SV) during heart failure. The current device design is being transferred to outside manufacturers in preparation for manufacturing devices for the first-in-human trial.

Company Milestones

- $6.1M Wellcome Trust Translation Fund Award from world's second largest medical foundation to support preclinical development
- 55+ successful minimally invasive deployments of the device using patented technology in 23 preclinical studies by 6 surgeons
- Successful 14-day preclinical studies in a large animal model of chronic heart failure, demonstrating safety and efficacy in the animals treated with the device compared to the control group
- Successful FDA funded proof of concept studies in animal with hearts analogous in size to those of 10 to 12-year old children
- 28 US and International Patents · 8 peer-reviewed publications since 2019, including 3 in 2023
- Device manufacture being transferred to professional outside vendors in preparation for first-in-human study

Team Members and Their Roles

William Altman, CEO
Boris Leschinsky, VP, Product Development
John C. Criscione, M.D., Ph.D., Co-Founder & Chief Technology Officer,
Christina Bolch, PhD, Principal Engineer
Keith Svagerko, VP, Administration and Business Development
Sonia Deggs, CPA
Jonathan Williams, Consultant
Dr. Iki Adachi, M.D., CorInnova's Pediatric Clinical Advisor

Ezalife : Designing simple, safe, securement methods to improve clinical outcomes and patient quality of life.

ezalife.com

IP Status: 3 provsional patents, 2 pending

Reference: 62/489,710, 62/636,536, 16/608,158, 62/771,963, PCT/ US2019/062469

Presentation: Ezalife

Ezalife is a University of Colorado startup that is is commercializg simple, safe, securement methods for a variety of transcutaneous medical devices. Our first product is a securement device for gastrostomy buttons (g-buttons) and cecostomy buttons (c-buttons). Surgical gastrostomy is the third most common non-cardiac, inpatient surgical procedure performed in children in the US. G-buttons are commonly placed in children to facilitate weight gain, correct nutritional deficiencies, hydrate, provide medication(s), and improve overall quality of life. Each year > 1M -buttons are placed or replaced in the US, and 3M globally. Placing a c-button is a similar surgical procedure in which a button is inserted into the first part of the colon to treat severe bowel dysmotility. The challenge with these buttons is that there is no device on the market to adequately secure them. All current solutions allow the button to move in the tract. This constant movement delays wound healing and leads to a variety of tract-related complications, such as granulation tissue formation, stomal enlargement with leakage, skin breakdown, skin infection, and accidental dislodgement—all of which are frustrating, time-consuming, and costly

Technology Overview

The Button Huggie is designed to secure—or hug—the button, keeping it in place and limiting its movement in the tract. With the Button Huggie, a g- or c-button is stabilized 24/7, even during feedings. It is also designed to simplify daily gauze replacement, reduce tract complications, prevent accidental dislodgement, and lower the cost of care. Our first prototype for AMT buttons includes three defining components: 1) a reusable lid; 2) a disposable, multi-functional base; and 3) a replaceable gauze sponge. The intelligently designed multifunctional base serves as a positioning feature during initial application, stabilizes the button while attaching the extension tube, and facilitates easy gauze changes with no need to remove and reapply tape every time. To replace the gauze, simply open the lid, slide out the soiled gauze, slide in a new sterile gauze pad, and then close the lid—a process that takes less than a minute. The FDA categorizes the Button Huggie as a Class II, 510(k) exempt medical device, subject to General Controls under Product Code ONY, regulated by the Code of Federal Regulations

Stage of Development and what the results are showing

We believe the first version of the Button Huggie is nearly ready for market. This version fits all AMT MiniONE buttons. We are currently enrolling subjects in a 200-patient Randomized Controlled Trial comparing the Button Huggie to tape and gauze securement of new g-buttons at Children's Hospital Colorado, but we are still early in the trial and do not yet have quantitative data. Our primary statistic that we are tracking via the study is rate of dislodgement, but other complications are also being tracked. We plan to use data from the trial to prove the Button Huggie's clinical value to key payers. We also plan to use feedback to further develop version two of the device, which will fit both AMT MiniONE buttons and Avanos MICKEY buttons.

Company Milestones

- [Q3-2017- Q2-2020] -Two PCT applications for Button Huggie in US ; international pending
- [Q2-2017], [Q1-2018] -Two pilot clinical trials to evaluate early prototypes
- [Q2-2019] - FDA confirmation that Button Huggie is 510k exempt
- [Q4-2019]- Global trademark protection for Button Huggie and EZaLife·
- [Q4-2019] - Worldwide license agreement with CU to commercialize Button Huggie
- [Q4-2021] - Closed pre-seed funding round of $850k
- [Q4-2022] - Hired first employee [Q4-2022]
- [Q4-2022] - Developed first injection molded prototype for Button Huggie
- [Q1-2023] - Enrolled first subjects in a 200-patient RCT at children's Hospital Coado

Team Members and Their Roles

Co-founder & CEO, Steve Moulton, MD
Co-founder & COO / CTO, Tyler Mironuck
Creative Director, Bryan Norman

PyrAmes Inc: Improving lives through better blood pressure measurement

IP Status: 10 Patents Issued, 1 Pending
Reference: Upon Request

www.pyrameshealth.com

Presentation: PyrAmes Inc

PyrAmes is a pre-revenue company spun out of Stanford developing wearable devices for continuous and non-invasive monitoring of blood pressure for patients of all ages. Our experienced 11-person team is based in Cupertino, CA. intervention.

Technology Overview

We use capacitive sensing to non-invasively capture pulse waveform data that is wirelessly streamed to mobile devices where accurate blood pressure values are derived through the use of machine-learning algorithms and displayed in real-time. Our devices are comfortable to wear and easy to use. They have been extensively tested on patients ranging from premature infants as small as 0.5 kg to 98-year old seniors.

Stage of Development and what the results are showing

Our Boppli (R) product for critically-ill infants received Breakthrough Device Designation from the FDA and has been submitted for 510(k) clearance as a Class II medical device. Data meet FDA guidelines for accuracy when compared against arterial line data taken simultaneously without external calibration. We have ongoing feasibility studies on products for toddlers, postpartum women, seniors, and preadmission/transport care.

Company Milestones

- Licensed by the California Food and Drug Branch to manufacture medical devices
- Boppli® for BP monitoring of NICU patients in pilot production and FDA review; tested on babies from 0.5 to 5 kg; recognized as a Breakthrough Device by FDA; 510(k) submission in Q4 2022; 510(k) clearance and market launch expected in Q4 2023.
- Sales/Distribution partnership with Sentec for Boppli
- Strategic investment from March of Dimes due to alignment on products for neonates and mothers at risk of complications from hypertensive disorders of pregnancy
- 2021 - Raised Series A

Team Members and Their Roles

Dr. Xina Quan, Co-Founder/CTO/CEO

Dr. Peter Noymer, Executive Chairman

Prof. Zhenan Bao, Co-Founder/Board Director

Will Sutherland, VP Operations

Dr. Keith Drake, VP Partnership Developm

Prapela Inc: Prapela helps babies breathe!

prapela.com

IP Status: 5 Issued Patents, 2 Patents Pending

Reference: US Patent No. 10258531, European Patent No. 2750593, Patent No. 10251552, European Patent No. 15719320.2, PCT/US 14/37115, U.S. Patent Application, 62/546,401

Prapela stimulation introduces a random signal, enhancing the detection of weaker signals, improving breathing rhythm.

Technology Overview

Rhythmic breathing is maintained by signals sent to and from the brain. Immature infant brains have difficulty detecting weak signals, causing irregular breathing. Prapela stimulation introduces a random signal, enhancing the detection of weaker signals, improving breathing rhythm.

Stage of Development and what the results are showing

1 Prapela technology used in 2 devices (a pad for hospital bassinets and a larger pad for incubators) for multiple medical indications. Prapela has submitted for De Novo from the FDA to treat opioid-exposed newborns. Supporting the De Novo application are two published studies, the most recent study with 180 newborns was published in JAMA Pediatrics on 5/15/23. In addition, an on-going clinical study at Tufts, UMass, Maine Medical and Cleveland Clinic is investigating the pads ability to reduce the incidence of neonatal opioid-withdrawal syndrome in opioid-exposed newborns. Following successful results in a published pilot study with preterm infants, on March 10, 2023 the NIH Blueprint Program awarded Prapela with a $3.5M grant to support a clinical study to improve the treatment of apnea of prematurity. The 125 patient study is expected to start in January, 2024. A soon to be published study with 10 preterm infants requiring ventilation support indicates patients experience improved oxygen uptake when laying on Prapela's pad..

Company Milestones

One unique technology - Stochastic Resonance for infant health
Two FDA Breakthrough Device Designations * Three time FDA Pediatric Device Consortium Award Winner
Four NIH SBIR grants * Five issued patents * Six years in operation (Delaware C Corp)
Seven million plus in Competitive Non-dilutive Grants

Team Members and Their Roles

John Konsin, CEO
David Morrill, VP of Product Development

ATTENDING ORGANIZATIONS

2Gether-International
2raze
AdvaMed
Akridge Ventures
American Gene Technologies
American Society of Clinical Oncology
Anzu Partners
ARPA-H
Association of University Research Parks (AURP)
Bank of America
Baker Botts
BARDA
BioBuzz Networks
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BioHealth Innovation/ Tallac Therapeutics
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Children's Hospital Los Angeles
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Early Light Ventures
Ecphora Capital
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