Section on Advances in Therapeutics and Technology Newsletter
American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®
Volume 14 • Issue 1 Spring 2024

Letter from the Editor

Welcome to the Spring 2024 edition of the SOATT newsletter! On behalf of the newsletter Co-Editors, we are pleased to host this newsletter as a forum for sharing new ideas and approaches to pediatric technologies and treatments.

In this edition, we have opened a new section of the newsletter. This section features recent publications with a technology or therapeutics theme published by our members. With over 1000 members (and growing, see the end of this newsletter for recent joiners!), we are excited to raise the profile and amplify the important and interesting work that you all are undertaking in service of pediatric care. This issue, we are featuring two publications submitted by Jonathan Davis and Sher Alam Khan. Take a look to learn more about their work, and if you have a recent publication, please let us know! We look forward to featuring your work in upcoming editions of this newsletter.

- This issue also celebrates the pediatric device prize winners from Fall 2023- read on to see the two awardees of $25,000 each from Southwest-Midwest National Pediatric Device Innovation Consortium and SOATT.
- In the Pediatric Device Spotlight section, learn about devices from Owlet, Boppli, and Prapela. These devices are all meant for use in infancy, though the technologies are unique as you can read more about.
- From iCAN, you can learn about recent activities and upcoming plans, including a session of "Ask the Experts" titled "Empowering Patient Journeys: Exploring Patient Engagement in Clinical Research with Mitch Herndon." See below for details on how to register for this event on May 18th, at 8 AM PST, 11 AM EST.

- The new Midwest Pediatric Device Consortium (MPDC) led by Nationwide Children's Hospital, Cleveland Clinic Children's Hospital, Cincinnati Children's Hospital, and The Ohio State University has launched! Read on for more details on this Consortium.
- For a perspective on therapeutics development, the Critical Path Institute's International Neonatal Consortium has formed a dedicated cell and gene therapy initiative. This initiative recently had its inaugural meeting, and you can read more about that meeting and what is planned later in this newsletter
- Finally, be sure to learn more about PedsMrkt, a marketplace and community platform that was spun out from the Center for Pediatric Innovation at Children's Mercy Kansas City.

With that, please dig in to the Spring edition of the newsletter!

Byron Alex
SOATT Newsletter Co-Editor
btalex@gmail.com

IN OUR ISSUE

Be Informed! Get Involved!

Join the Section on Advances in Therapeutics and Technology Listserv® Today!

If you are interested in joining the Listserv, email Eleni Victoria at evictoria@aap.org

New Section!

Recent Publications in Therapeutics and Technology

***SOATT Member Submitter**

Prevalence of Immunization Status, Complications and Outcome in Children Admitted with Measles Tertiary Care Hospital

Authors: Muhammad Sohaib Khan, Mian Sohail Adnan, **Sher Alam Khan**, Khawaja Bushra Noor, Aleena Anees, Maira Nazar
Journal: Journal of Population Therapeutics & Clinical Pharmacology
DOI: https://doi.org/10.53555/jptcp.v31i1.3929

Rapid Whole-Genomic Sequencing and a Targeted Neonatal Gene Panel in Infants With a Suspected Genetic Disorder

Authors: Jill L. Maron, MD, MPH; Stephen Kingsmore, MD; **Jonathan M. Davis**, MD; et al.
Journal: JAMA
DOI: 10.1001/jama.2023.9350

Recent Recognitions:

- Associated Press - AP News: A broad genetic test saved one newborn's life. Research suggests it could help millions of others
- Ten Best Genomic Papers Published in 2023
- The Clinical Research Forum - 2024 Top 10 Clinical Research Achievement Awards

Fall 2023 SWPDC and AAP Section on Advances in Therapeutics and Technology (SOATT) Pediatric Device Prizes

Chester J. Koh, MD, MBA, FACS, FAAP and Brandon Hunter, MD

Texas Children's Hospital, Baylor College of Medicine,
and the Southwest-Midwest National Pediatric Device Innovation Consortium (SWPDC.org)
Email: ckoh@bcm.edu
Email: rxhunter@texaschildrens.org

A great need currently exists for medical devices designed specifically for children, which is most likely a result of economic, clinical, and regulatory challenges, as well as a lack of established mechanisms for joining pediatric device ideas with qualified individuals/programs and industry partners to create innovative and needed pediatric devices. The Southwest-Midwest National Pediatric Device Innovation Consortium (SWPDC.org) is one of the FDA-grant-supported Pediatric Device Consortia (PDC) that serves as a resource for pediatricians, pediatric caregivers, pediatric specialists, engineers, and entrepreneurs in developing their innovative pediatric medical devices. The annual SWPDC and AAP SOATT Pediatric Device prizes were created to help foster the innovation of pediatric devices specifically designed for children. These annual prizes were initiated in 2021 after approval by the SOATT Executive Committee.

The winners of the SWPDC and AAP SOATT Pediatric Device Prizes for Fall 2023 were:

$25,000 – KidTech, Inc. – Bo Hood (Houston, TX)
NeoLite X is an easy-to-use phototherapy solution with real-time support data for infants with jaundice

$25,000 – Vascular Perfusion Solutions, Inc. – Somer Baburek (San Antonio, TX)
VP.S ENCORE is a portable cardiac preservation device for pediatric heart failure patients during cardiac transplantation

We congratulate the winners of the Fall 2023 awards! The next award cycle will take place in Fall 2024, and we encourage all pediatric device innovators in the AAP SOATT to apply.

We also wish to thank our SWPDC staff (Christine Luk, Brandon Hunter, Jhalak Mehta and Soniya Nai) and the SWPDC leadership team, as well as the review committee that included Soo Kwon, MD, FAAP, Yale University and AAP SOATT Executive Committee member, for their assistance with the application review.

About SWPDC: The Southwest-Midwest National Pediatric Device Innovation Consortium (SWPDC) is a multi-institutional consortium that is supported by a FDA Pediatric Device Consortia (PDC) P50 grant (Koh – Contact PI), and is based at Texas Children's Hospital and Baylor College of Medicine, Texas A&M University, Rice University, University of Houston, and University of Minnesota. SWPDC is dedicated to improving children's health by supporting pediatric device innovators to create novel pediatric medical devices with local, regional, and national institutional and innovation partners. There are five national consortia at tertiary children's hospitals in the U.S. Of note, assistance provided by SWPDC, including the award above, are provided in a non-dilutive, "no-strings-attached" manner. SWPDC provides direct device / seed funding, consulting assistance, engineering and design assistance, potential clinical collaborators, and connections to local programs and resources. Please visit SWPDC.org for more information.

Pediatric Medical Device Resource List

FDA-grant-supported Pediatric Device Consortia (PDC) – a resource for pediatricians, pediatric caregivers, pediatric specialists, engineers, and entrepreneurs in developing their innovative pediatric medical devices. A new five-year cycle began in September 2023, with the updated consortia sites listed below. Available assistance can include consulting, project management, and seed funding.

Further details can be found in the previous editions of the newsletter on the Section website: https://services.aap.org/en/community/aap-sections/advances-in-therapeutics-and-technology/

FDA Pediatric Device Consortia Grants Program
(Office of Orphan Products Development)
https://www.fda.gov/industry/developing-products-rare-diseases-conditions/pediatric-device-consortia-grants-program

Alliance for Pediatric Device Innovation (formerly National Capital Consortium for Pediatric Device Innovation)
(Children's National Health System / University of Maryland)
innovate4kids.org

Southwest National Pediatric Device Innovation Consortium
(Texas Children's Hospital and Baylor College of Medicine / University of Minnesota / Texas A&M / Rice / Univ. of Houston)
SWPDC.org

Consortium for Technology and Innovation in Pediatrics
(Lurie Children's Hospital)
www.westcoastctip.org

University of California San Francisco-Stanford Pediatric Device Consortium
(University of California San Francisco / Stanford University)
pediatricdeviceconsortium.org

Midwest Pediatric Device Consortium (MPDC)
(Nationwide Children's Hospital / Cleveland Clinic Children's Hospital / Cincinnati Children's Hospital)

Foundation for NIH Public-Private Partnerships
Pediatric Medical Devices Design Phase - (evolved from SHIP-MD)
https://fnih.org/our-programs/pediatric-medical-devices-design-phase/

Pediatric Device Spotlight

Owlet's BabySat Pulse Oximeter Accuracy Study

Alisa Niksch, M.D., Pediatric Cardiologist/Electrophysiologist and Senior Director Medical Affairs at Owlet Baby Care, Inc.

Every year in the United States, nearly 40,000 babies are born with a congenital heart defect (CHD)[1]. Even further, according to the CDC, about 1 in 4 of those babies suffer from a critical CHD and need major surgery or other life-saving procedures during their first year, or even hours, of life.

These defects, if not identified before birth, can be identified through a careful physical exam, and a vital sign assessment, including extremity blood pressure differentials and pulse oximetry screening. Pulse oximetry has become an integral element of critical congenital heart disease (CCHD) screening, a protocol which has been implemented in all 50 states and Washington, D.C. since 2018. CCHD screening procedures, which have been refined over a period of years, have been incredibly valuable in ruling out cardiac disease in newborns. With a 99% specificity, it has demonstrated a low false positive rate. However, this screening has been observed to possess an only moderate sensitivity of 76.5% (Plana MN, et al. Pulse oximetry screening for critical congenital heart defects. Cochrane Database Syst Rev. 2018 Mar 1;3(3):CD011912) for critical forms of CHD; studies of late diagnosis of CHD demonstrated that pulse oximetry screening predominantly missed infants with either Tetralogy of Fallot or Coarctation of the Aorta (Ailes, et al. Pediatrics (2015) 135 (6): 1000–1008.).

The era of prenatal diagnosis has lessened some of this risk for CHD, but has not removed the risk of hypoxia from neonatal lung disease or persistent pulmonary hypertension. Limitations in screening capabilities can severely delay treatment, leading to worse outcomes or increased neonatal mortality. For example, delayed diagnosis of neonatal hypoxemia can cause adverse life-long consequences such as impaired cardiac function and neurodevelopmental impairment.

The solution for identifying these conditions may lie with the ability to monitor patients at home, after an infant has been discharged with a seemingly clean bill of health. There are already demonstrable advantages to home monitoring for infants who have baseline hypoxia to manage their treatment plan and provide timely intervention when needed.

However, evaluating the accuracy of pulse oximeters in an at-home setting while factoring in infant motion, skin tone, placement of the sensor, and adverse events due to skin contact, which are all known to decrease efficacy of oxygen saturation readings, has been a significant need to make monitoring effective for this population.

The BabySat™ Monitoring System

Developed by Owlet, the BabySat monitoring system is an FDA-cleared, prescription pulse oximeter for at-home use. BabySat features Owlet's wire-free sock design that secures a sensor to the baby's foot and measures saturation of peripheral oxygen (SpO2) and pulse rate readings and transmits these readings wirelessly through low energy bluetooth technology to the system's base station.

[1] https://www.cdc.gov/ncbddd/heartdefects/data.html#print

continued on Page 7

This base station monitors an infant's health readings and triggers alarms if the readings are outside specific limits as determined by the patient's care team. The base station also relays the data to Owlet's mobile Care+ App via a secure cloud server which displays the readings and any alarm activity to a home user.

As part of the FDA clearance process, rigorous testing of BabySat was performed to demonstrate its accuracy against hospital-grade standards, as well as the safety of its form factor for an infant population. In addition to formal testing of the device against arterial co-oximetry in a hypoxia lab to ensure that BabySat met all required ISO standards and demonstrated equitable accuracy across a full range of skin tones, additional evaluation was needed in infants in the home. This study complemented baseline accuracy testing to exhibit the device's performance within the intended use environment.

Testing Across All Skins Tones and Ankle Circumferences
Several factors have been shown to influence the accuracy of pulse oximetry. Importantly, recent evidence suggests that the accuracy of pulse oximetry deteriorates in subjects of darker skin pigmentations, specifically demonstrating a positive bias and underestimating the degree of hypoxia in these individuals.

To evaluate the accuracy of BabySat in infants across lighter and darker skin tones, a comparable analysis was carried out using BabySat and Masimo's Radical 97 pulse co-oximeter. These analyses found that neither skin tone, nor ankle circumference influenced the precision of the SpO2 readings of BabySat. This analysis confirmed the accuracy of BabySat comparable to other similar FDA-cleared products on the market.

Accuracy Across Varying Degrees of Motion
In addition to its other features, BabySat has an embedded accelerometer that can quantify motion and incorporate motion data into reading quality. Motion has been known to induce considerable error into pulse oximetry accuracy. To determine the influence of motion on the readings recorded by BabySat, another comparative analysis with the Masimo Radical 97 was carried out throughout an array of typical active and passive infant activities such as sleeping, feeding, diaper changing, rocking etc. Quantitative measures of motion from BabySat were able to show a significant difference in motion levels among infants that were asleep vs. awake. Documented periods of higher motion were able to be correlated with reliable pulse rate and SpO2 readings from BabySate. Accuracy of SpO2 readings from BabySat during motion did not deteriorate compared to the reference device, which is also labeled for measurement through motion.

Conclusion
While the importance of continual home monitoring of vital signs in vulnerable neonates and infants has been demonstrated in several studies, the accuracy of these readings have been shown to be influenced by several factors, such as skin pigmentation, motion and sensor placement. The demonstration of accuracy of Owlet's pulse oximetry technology compared to co-oximetry measurements is an essential component to meet regulatory clearance requirements. However, this testing alone is not sufficient to demonstrate the efficacy of a device in an infant population with specific characteristics and monitoring requirements. Validation of this device in the population and environment of use was an essential approach to make it relevant for the unique monitoring challenges infants present for clinicians.

To learn more about Owlet's BabySat Accuracy study, please download the whitepaper here.

Trademarks and brand names are the property of their respective owners.

continued on Page 8

Boppli®, a wearable continuous, non-invasive blood pressure monitor for neonates

Anoop Rao MD, MS, Clinical Assistant Professor, Pediatrics (Neonatology) Lucile Packard Children's Hospital, Stanford University School of Medicine

Boppli® is a wireless, wearable device that provides continuous, non-invasive blood pressure monitoring (cNIBP) for neonates. It can be attached like a wristwatch on the arm or foot of a neonate and addresses the challenges inherent in blood pressure monitoring for premature infants. Traditional methods, such as invasive catheterization and cuff-based techniques, have long been associated with risks and discomfort. Boppli introduces an innovative capacitive sensing technology that fundamentally transforms the standard of care for neonates.

Central to Boppli's design is its sophisticated sensor array, engineered to conform gently to the contours and delicate skin of premature infants. This thin, flexible array, coupled with low-power electronics, facilitates precise and continuous monitoring while maintaining infant comfort. Through advanced signal processing and proprietary and robust statistical algorithms, Boppli derives systolic, diastolic, and mean arterial pressure, providing healthcare professionals with reliable data for clinical decision-making. With its compact, lightweight form factor, and biocompatible foam band for use on intact skin, Boppli offers an attractive solution for neonatal ICUs.

Boppli is the first FDA-cleared cNIBP device for neonates and was developed by Pyrames Inc. (Cupertino, CA) in collaboration with Dr. Anoop Rao, a neonatologist at Stanford. Their work has been supported in part by grants from the National Institute of Health (NIH), the National Capital Consortium for Pediatric Device Innovation (NCCPDI), the Children's Research Institute and Stanford's Maternal Child Health Research Institute (MCHRI), the Southwest Pediatric Device Consortium (SWPDC), the American Academy of Pediatrics (AAP) Section on Advances in Therapeutics and Technology (SOATT), and the West Coast Consortium for Technology & Innovation in Pediatrics (CTIP). An additional multicenter study was conducted at Children's National, Texas Children's, Tufts, Stanford LPCH, and Alberta Children's to further validate its accuracy, safety, and efficacy. Please contact Dr Anoop Rao (anooprao@stanford.edu) for research collaborations and Dr Xina Quan (xquan@pyrameshealth.com) for commercial queries.

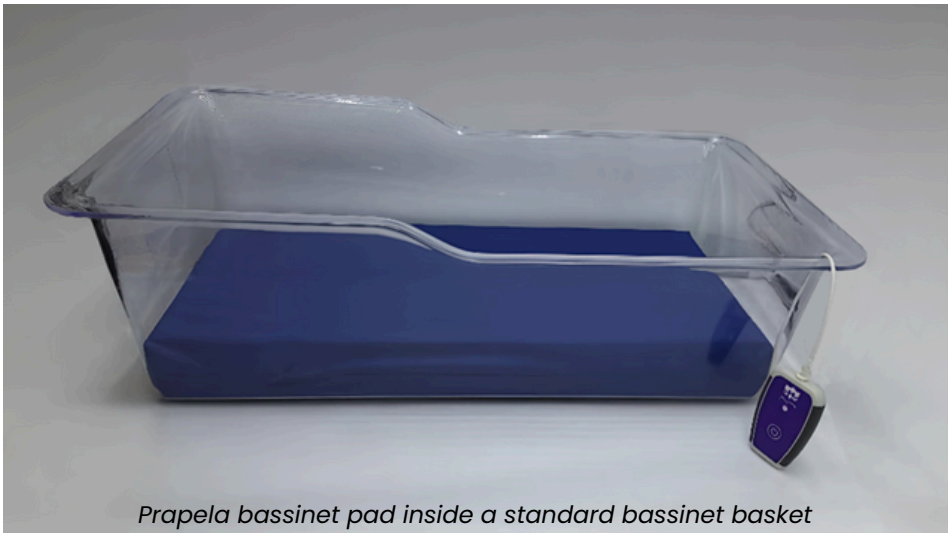
continued on Page 9

Prapela® – A Breakthrough Stimulation to Improve Breathing in Neonates

John Konsin Co-Founder & CEO

Improving respiratory control in neonates remains an elusive challenge. Whether dysregulated breathing is caused by neurological immaturity in preterm infants or following prenatal opioid exposure with term infants, existing treatment options are limited and only partially successful.

Prapela, an emerging pediatric medical device company, is working to provide a new, noninvasive stimulation therapy to promote regular breathing and stabilize oxygen fluctuations in neonates. Prapela's therapy is delivered from a reusable mattress pad for incubators and bassinets. The pad produces a precise stimulation that is barely perceptible to the touch and ear, and an early study indicates it has no significant effect on sleep cycles. The stimulation is nonrepetitive, reducing the potential for habituation. Nothing is attached to the infant, and the pads can be covered with standard hospital linens. Touching the hand-held controller's on/off button activates the single setting stimulation, making the pad simple and easy to use.



Prapela bassinet pad inside a standard bassinet basket

The mode of action provided by the Prapela stimulation is a unique, stochastic vibration designed to resonate at the mechanoreceptor nerve endings, boosting the neurological mechanisms that regulate neurobehavioral systems. This premise is supported by published studies that began 40 years ago when Professors Mackey and Glass at McGill University proposed that small inputs can cause significant functional improvements in physiological control systems. In 1997, stochastic resonance (SR) was introduced to neonatology when Drs. Paydarfar (co-founder and Scientific Advisor to Prapela) and Buerkel first reported that stochastic stimulation improved respiration in a preterm newborn. Twelve years later, Dr. Richard Martin's editorial indicated that results from an investigational study with Prapela's stimulation "holds great significance in promoting nonpharmacological interventions to improve neonatal outcome."

Thanks to a recent grant from the National Institutes of Health (NIH) Blueprint MedTech program, Prapela is advancing this novel stimulation to make it available to neonatal intensive care units throughout the United States. A new clinical trial expects to demonstrate that Prapela's pad significantly reduces apneic events in preterm newborns when used adjunctively with FDA-recommended dosing for caffeine citrate. Further, the number of days infants require respiratory support is expected to decline. Clinicians are also likely to spend less time providing reactionary manual stimulation to terminate apneas and reduce interrupting their patients' sleep. Finally, potentially fewer alarms in the NICU will be a welcome relief for caregivers who provide unyielding patient support.

Patient recruitment begins this Spring at Tufts Medical Center and the University of Alabama at Birmingham. After a 24-hour baseline period for data collection, preterm newborns between 22w 0d to 32w 6d gestational age (GA) will be enrolled in a randomized controlled masked trial.

continued on Page 10

Enrollment is expected to exceed over 100 infants and last for several months. Where other approaches have failed (remember oscillating water beds?), Prapela aims to introduce the first pad to reduce apnea episodes and intermittent hypoxia.

Prapela is also working with Tufts to report findings on a recent clinical study with prenatally opioid-exposed (POE) newborns. Following cessation of maternal drug transfer at birth, newborns can develop a postnatal withdrawal condition called neonatal opioid withdrawal syndrome (NOWS). Infants with NOWS experience dysregulated control of their autonomic nervous system, movement & muscle tone, sleep/wake state, and sensory processing. Results from the study will report on the effectiveness of Prapela's pad used in a bassinet immediately after birth to reduce the incidence of NOWS in POE newborns. This study follows a recent independent study by Bloch-Salisbury et al., which concluded as adjunctive therapy to concurrent medical treatment for newborns with POE, Prapela's stimulation reduces pharmacotherapy and length of pharmacotherapy treatment. Specifically, infants in the stimulation group received 1.76 mg/kg less morphine and completed treatment in 3.2 fewer days.

Since 2017, the company has been honored to win numerous awards and grants. The FDA has twice awarded Prapela with a Breakthrough Device Designation. The NIH has provided over $6 million to accelerate the development and commercial availability of the technology.

The company was awarded first prize in the Ohio Opioid Technology Challenge and is a multiple-award winner in the FDA-sponsored Pediatric Device Consortium program. Prapela's stimulation has been evaluated at ten leading medical centers, and no adverse events have been reported due to the stimulation.

For the next steps, the company is preparing its De Novo submission to the FDA for the bassinet pad and, later, the incubator pad. From the Latin, De Novo means "anew," and this FDA regulatory path requires Prapela to submit extensive data supporting the clinical efficacy and safety of the device. The company aims to provide affordable, easy-to-use devices that improve outcomes and are easily integrated with existing management strategies to improve dysregulated breathing and stabilize oxygenation.

Beyond these next steps, Prapela will continue exploring additional applications of its unique therapy with clinicians and regulators in the United States and worldwide. Prapela believes its technology can potentially help millions of newborns and caregivers annually.

For more information on Prapela and this breakthrough noninvasive stimulation therapy, please visit www.prapela.com.

*Prapela is a registered trademark of Prapela, Inc., Biddeford, Maine, USA

Empowering Pediatric Advisors Worldwide: iCAN's Latest Updates and Inspiring Achievements

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iCAN, is the premier global pediatric platform empowering the patient voice in healthcare, driven by youth for youth. As a worldwide consortium of 36 KIDS'(Kids Impacting Disease through Science) advisory groups spanning four continents, including one virtual chapter, iCAN's dedicated youth member groups work in unison around the world to provide a voice for children and families in medicine, research, science, and innovation, with a goal of fostering greater global understanding about the importance of the pediatric patient and caregiver voice in healthcare, clinical trials, and research. On average, our youth are ages 8-18 years old, most of whom are living with chronic, rare, and complicated diagnoses, though a few of our youth have no medical diagnoses or medical conditions. iCAN values and understands that all patients, even the youngest, often have ideas that can help improve their healthcare experiences. To foster diversity, all children from anywhere may freely join iCAN. iCAN also supports young adults and the voice of parents, many of whom have young people who are unable to share their voices. Whether you are a patient, family member, healthcare professional, or supporter of the cause, we welcome you to visit our website at icanresearch.org to learn more about our mission, various programs, and initiatives. Join us in the effort to ensure that every child's voice is heard and their unique experiences are taken into account to improve healthcare outcomes for all pediatric patients.

If you're passionate about transforming the pediatric landscape and eager to support iCAN's mission, we invite you to consider sponsorship or partnership opportunities. Reach out to us at sabinaschmidtgoldstein@icanresearch.org to explore how together, we can make a meaningful difference in the lives of children worldwide. Join us in shaping a brighter future for pediatric healthcare.

continued on Page 12

Registration is Open for iCAN's 2024 Annual Research and Advocacy Summit Presented by Jumo Health!

Central to our annual calendar is the iCAN Research & Advocacy Summit, a hallmark event that serves as a convergence point for research, science, medicine, and camaraderie. Drawing global participants, our KIDS youth members showcase their research projects, engage in hospital service projects, and participate in direct discussions with industry and panelists on various aspects of pediatric care. Through these efforts, iCAN continues to foster a global community of young advisors dedicated to improving pediatric healthcare worldwide.

To sponsor our summit visit bit.ly/iCANsponsorships

To register for our Summit visit bit.ly/iCANSummit24Registration

The anticipation among our youth members is palpable as they eagerly await this remarkable event. But, to make it truly unforgettable, we need your support! So, if you believe in empowering and prioritizing the pediatric patient perspective, we invite you to be a part of this life-changing event. You can contribute in two meaningful ways:

1. Sponsor the 2024 Summit: Your sponsorship plays a pivotal role in the seamless organization of the summit. Your generous support ensures an impactful experience for all attendees.
2. Sponsor a Child to Attend: Your sponsorship directly impacts a child's life, granting them the chance to attend the summit in Bari. Covering travel, accommodation, and participation, your support offers a world of learning and empowerment.

Thank you for considering this opportunity to support the next generation of healthcare leaders. Your generosity and dedication are deeply valued. Let's unite in Bari, Italy, to create a summit experience that empowers young minds for years to come!

continued on Page 13

Global Participation in the iCAN Challenge of 10: A Milestone Celebration of Pediatric Engagement

Sponsor our youth members' challenges at https://bit.ly/iCANchallengeof10

In celebration of our 10th anniversary, we held our inaugural iCAN Challenge of 10, drawing participation from chapters spanning the globe, including KIDS Walter Payton, Albania, Uganda, Virtual, and Rady. The iCAN Challenge of 10 provided our youth with a platform to select and pursue challenges under the overarching theme of "10." Participants enthusiastically embarked on their challenges, ranging from physical feats to creative projects, each intricately aligned with their unique interests and capabilities. Moreover, participants actively sought sponsorship to facilitate their attendance at our Annual Research & Advocacy Summit, this year hosted in Bari, Italy. The funds raised through sponsorship and donations contribute directly to enabling more children to participate in the Summit, ensuring that 100 percent of the proceeds are dedicated to this purpose. This collaborative effort not only fosters community engagement but also increases awareness for pediatric causes on a global scale.

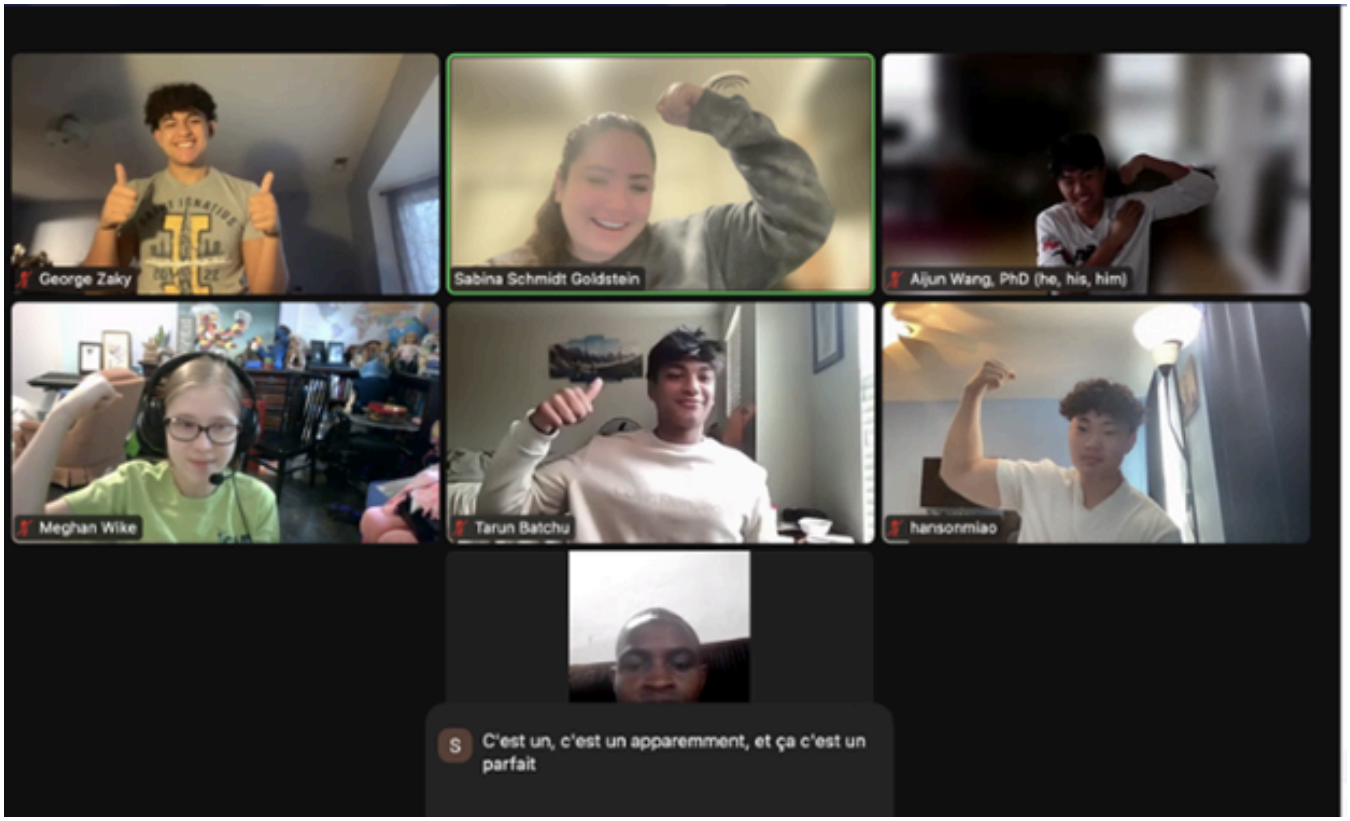
KIDS Walter Payton Chapter enthusiastically embraced the iCAN Challenge, creating 10 engaging and informative research videos on Instagram. Notably, one video delved into the opioid crisis, shedding light on overdose concerns while also educating viewers on the life-saving potential of Narcan Nasal Spray. Their dedication to raising awareness through innovative mediums was commendable.

Meanwhile, KIDS Albania devised a heartwarming challenge aimed at spreading the joy of reading by gifting 10 books to 10 children. Their initiative not only promoted literacy but also ignited smiles and appreciation within their community, showcasing the transformative power of generosity.

continued on Page 14

In a display of remarkable endurance, KIDS Uganda undertook the challenge of running a mile daily for 10 consecutive days. Sponsored by the Pediatric Trials Network (PTN), their perseverance underscored the profound impact of collaborative support in achieving ambitious goals.

Across digital realms, KIDS Virtual embarked on a 10-day journey of physical activity, exemplifying the importance of staying active and healthy! Their dedication to promoting well-being resonated as a testament to the vitality of holistic health education.



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Meanwhile, KIDS Rady created the "10x10 School Ready Backpacks" challenge, where 10 members each filled 10 backpacks with school supplies for children in need, totaling an impressive 100 backpacks donated. Additionally, their fundraising efforts at Handle's Homemade Ice Cream exemplified their commitment to supporting fellow chapters, specifically KIDS Uganda, to come to the Summit.

The collective efforts of participating chapters in the iCAN Challenge of 10 exemplify the transformative potential of pediatric engagement, underscored by innovation, compassion, and collaborative spirit.

iCAN Youth Member Spotlight!

Spotlight on Lindsay Carstairs, 2024 Military Child of the Year® for the Navy, Co-Founder of KIDS Rady, and Rising Tulane University Student

Meet Lindsay Carstairs, a remarkable young individual whose journey exemplifies resilience, compassion, and unwavering determination. At just 18 years old, Lindsay has already achieved remarkable milestones and garnered admiration for her altruistic spirit.

Born into a family rooted in service, Lindsay is the daughter of Navy heroes Shaun and Keri Carstairs, who have instilled in her a profound sense of duty and empathy. Lindsay's path took an unexpected turn when she was diagnosed with Jeavons Syndrome, a rare form of epilepsy, at the tender age of 8.

Despite the challenges posed by her diagnosis, Lindsay refused to be defined by it. With unwavering support from her family, particularly her older brother Ian, Lindsay emerged as a beacon of hope and resilience. Drawing from her parents' medical expertise, Lindsay navigated the complexities of her condition with grace and determination.

Among Lindsay's many accomplishments is her co-founding of the KIDS-Rady San Diego chapter, a testament to her commitment to supporting children facing similar challenges. Reflecting on this endeavor, Lindsay expresses, "Creating this community resource has been a dream realized, teaching me invaluable lessons in organization and advocacy."

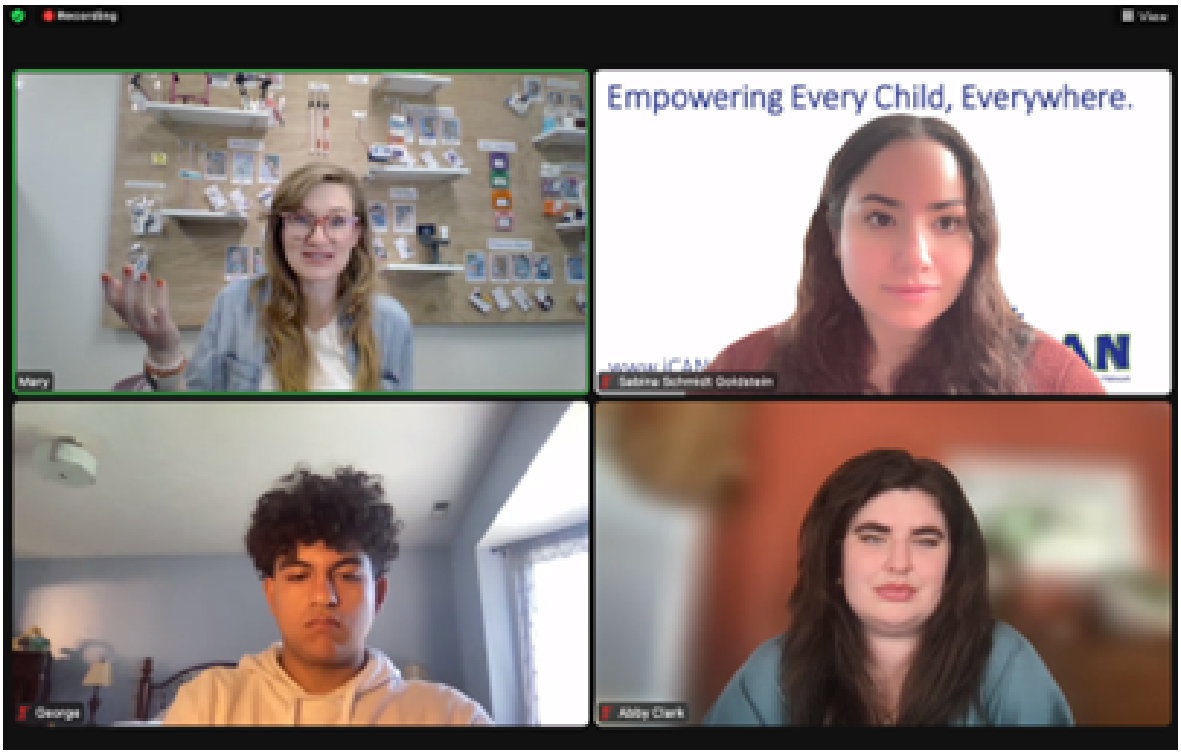
continued on Page 16

But Lindsay's impact extends beyond the realm of healthcare advocacy. A dedicated member of the Canyon Crest Academy varsity girls' flag football team, Lindsay's leadership and tenacity on the field mirror her compassionate nature off the field. Her exemplary service has been recognized with the prestigious President's Gold Volunteer Service Award, underscoring her unwavering dedication to making a difference in the lives of others.

Looking ahead, Lindsay is poised to embark on a new chapter of her journey as she enters Tulane University as an Honors Scholar. With a keen interest in political science, international relations, and marketing, Lindsay is eager to continue her mission of effecting positive change on a global scale.

April Ask the Experts - April Recap and Looking Ahead

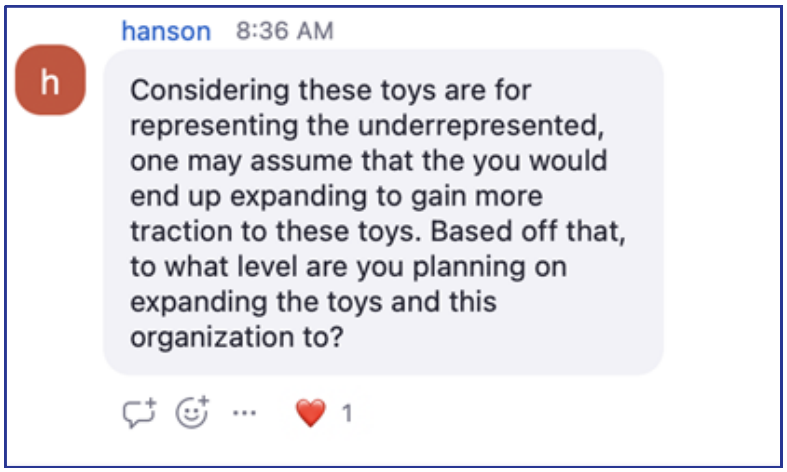
Empowering Children through Play: Mary Jenner, RN, Shares Insights in Ask the Experts Session

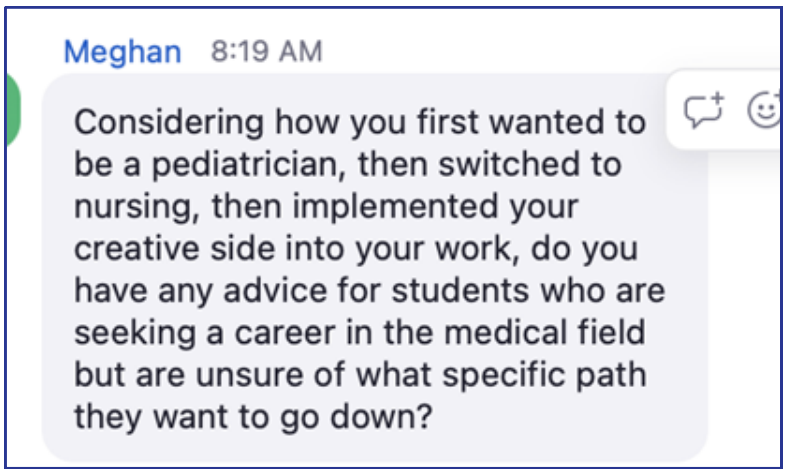


On April 6th, the latest installment of the monthly Ask the Experts series took place, captivating our youth members with the inspiring journey and insights of guest speaker Mary Jenner, RN. Jenner, acclaimed author of "The Butterfly Pig," and founder of a groundbreaking toy medical device company, graced the virtual stage, eager to share her wisdom on empowering young patients.

Jenner's journey from author to entrepreneur began with her book, "The Butterfly Pig," which not only entertained children but also planted the seeds of curiosity and empowerment. Building on this foundation, she ventured into the realm of healthcare innovation, founding her own toy medical device company.

continued on Page 17





During the session, Jenner recounted heartwarming anecdotes of the profound impact her toy medical devices have had on young patients. These innovative tools not only familiarize children with medical procedures but also empower them to take ownership of their treatments. By allowing children to simulate medical scenarios and articulate their experiences, these toys bridge the communication gap between young patients and healthcare professionals.

One of Jenner's most poignant revelations was the transformation she witnessed in children who used her devices. By engaging in play, these children gained confidence and agency, enabling them to articulate their needs and fears to healthcare providers effectively. Jenner emphasized the importance of empowering children to actively participate in their healthcare journey, stressing that fostering such autonomy from a young age lays the foundation for a lifetime of informed decision-making.

Beyond her groundbreaking inventions, Jenner imparted invaluable advice to the young audience, encouraging them to seek out opportunities aligned with their interests. Drawing from her own experiences, she highlighted the importance of curiosity and exploration in personal and professional growth. By urging children to embrace their passions and pursue meaningful experiences, Jenner inspired a new generation to unlock their full potential.

Mary Jenner's appearance on our Ask the Experts offered a compelling narrative of innovation, empowerment, and the transformative power of play. Through her pioneering work and impassioned advocacy, Jenner continues to reshape the landscape of pediatric healthcare, leaving an indelible mark on the lives of young patients worldwide.

Midwest Pediatric Device Consortium

Cory Criss, David Eckmann, and McKay Noll

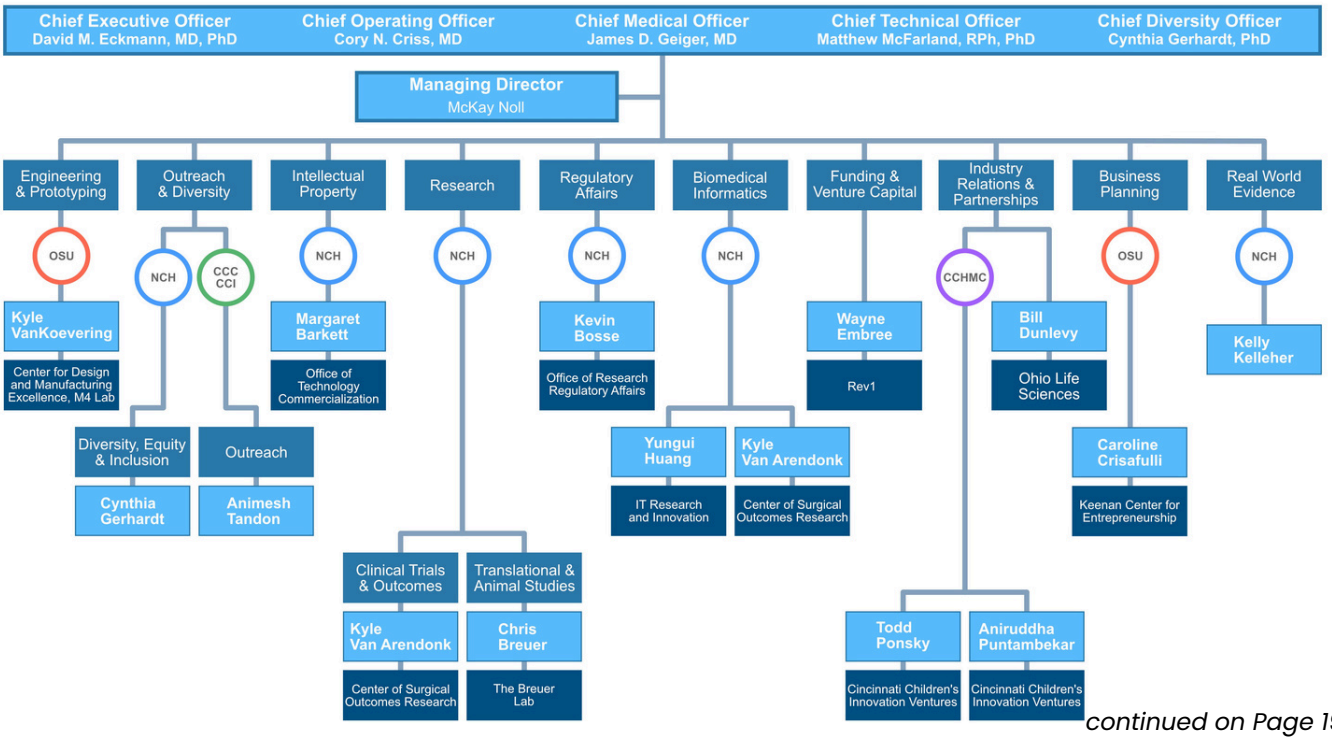
The Midwest Pediatric Device Consortium (MPDC) is a new consortium lead by Nationwide Children's Hospital, Cleveland Clinic Children's Hospital, Cincinnati Children's Hospital, and The Ohio State University. The MPDC has a mission to leverage the expertise and resources of the region to facilitate pediatric device development. Consortium members serve the premier institutions and industries whose partnership, including sharing of knowledge and resources, enables the development of pediatric medical devices. MPDC members include Ohio's most well-known, respected medical and academic institutions with a collective reach and connection with manufacturers that position them to advance innovative ideas into usable pediatric devices that are rapidly available in the national marketplace.

MIDWEST PEDIATRIC DEVICE CONSORTIUM

The MPDC is the first of its kind in the Midwest and is supported by a $6.95 million grant from the Food and Drug Administration (FDA), and incorporates many of the other major health care centers, academic institutions and industries across the Midwest. With the knowledge and support of industry leaders committed to the MPDC, the number of pediatric medical devices across the nation will continue to increase. The MPDC has various unique characteristics that are highlighted below.

<u>Organization Structure</u>

The MPDC offers a unique and individualized approach focused on device development outcomes. Our unique administrative and organizational structure, built as an academic/industry hybrid model, facilitates our focus on commercialization, regulatory navigation, trial implementation, individualized mentorship, and a commitment to diversity, equity, and inclusion.



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This approach makes the MPDC distinctive for impact in bringing new technologies and products into pediatric care. We have implemented a model that brings direct focus to the needs of the individual inventor by creating a specialized departmental structure of consortium-member experts. Additionally, our reliance on commercialization, industry partnership, and venture funding will undoubtedly be an important contribution to the PDC network.

The MPDC is uniquely structured to provide internal resources catered to inventors along any stage within the Total Product Life cycle. The organizational structure involves an Executive Committee overseeing the efforts, and individual Departments focused on specific expertise. This allows utilization of resources such as the Center for Design and Manufacturing Excellence at The Ohio State University, the Regulatory Office at Nationwide Children's Hospital, Cincinnati Children's Innovation Ventures, and Cleveland Clinic Innovations, just to name a few.

Commitment to the Customer

Additionally, part of the intake and review process is meeting with our dedicated Needs Assessment Committee (NAC). This highlights our commitment to evaluating each inventor's specific needs and filling the gaps with MPDC resources. The committee utilizes the feedback from the pool of Advisors and other PDCs across the country, and leverages the expertise in the areas of entrepreneurship, healthcare, regulatory, intellectual property, venture capital, and engineering. The NAC will point inventors towards the Departments of expertise as mentioned above, for a focused-approach. The NAC can then provide service driven resources to fil these gaps and mentor and coach inventors to the next steps. This is a customer-focused model and serves the needs of each individual project. The MPDC is focused on expanding their portfolio and providing services for all members, regardless of receiving funding.

Collaboration

There is a major commitment from the MPDC to collaborate across the member institutions, partners, and the other PDC sites. The MPDC has plans to not only collaborate with the other PDCs on research studies, combined funding mechanisms, but also initiatives such as real world evidence, clinical trials building, and health equity.

Funding Opportunities

The MPDC currently provides an intake and review process directed towards the Direct Device Funding mechanism. This is a yearly application process directed towards companies focused on a pediatric device project. The current cycle is once a year and involves a review by the Advisory council, which is made up of over 80 advisors that represent healthcare, IP/regulatory, business planning, engineering/prototyping, community, and venture. Following the review, applicants are awarded funding up to $50,000/year/project. The MPDC is also interested in taking this a step further and providing a commitment to provide services to catalyze the companies to support local industry, and resources to translational projects within the MPDC institutions. These awardees are then assigned a project manager to continue coaching and resource allocation during the funding cycle. Additionally, the investment team will meet with the awardees to discuss additional fundraising opportunities in the region.

Clinical Trials Infrastructure

One of the major challenges for companies navigating the pediatric space is access to clinical data and clinical trials implementation. This is generally a necessary step towards achieving regulatory requirements and commercialization. Utilizing the resources within the four institutions, the MPDC Is building the clinical trials network and infrastructure to provide this resource to inventors across the country.

continued on Page 20

Additionally, The MPDC has recently joined the FNIH Pediatric Medica Design Phase, which is focused on addressing the challenges of clinical trials and implementation for pediatric medical devices.

Real World Evidence

Another area of focus remains understanding and providing clinical data for companies interested in expanding labeling, market evaluation, and observational data. The MPDC is collaborating with the other PDCs on RWE, and have plans to build a RWE task force focused on providing quality data access tied to regulatory needs. This is lead by current leaders in the field who leverage the comprehensive resources in the region.

Website and Resources

The MPDC is in the process of building an external website that will provide not only educational resources and updates on funding opportunities, regulatory news, and inventors spotlights. Additionally, it will serve as a hub for their health equity initiative, intake and review process, and access to a deal flow database for MPDC partners and advisors.

In just over 6 months, the MPDC has already finished their first funding cycle and are planning to announce the awardees within the next week. For the upcoming year, expect a new website, resources, showcase event, and collaboration with the other PDCs.

The Critical Path Institute: International Neonatal Consortium Cell and Gene Therapy Initiative

Christine Barry, MPH, Gina Calarco Smith, MPH, RN, Kanwaljit Singh, MD, Klaus Romero, MD
Pediatrics Program, Critical Path Institute
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Cell and gene therapies have been an exciting breakthrough promising hope for many families with hereditary, congenital, and genetic abnormalities that result in health problems or, in the severest forms, are incompatible with life. The development of these regenerative therapies come with ethical, scientific, and operational challenges to conducting clinical trials and understanding the regulatory evidentiary considerations for these innovative therapies to be available to the patients and families that need them. When considering regenerative therapies (aka cell, gene, molecular targeted therapies) that offer potentially significant disease-modifying effects, drug developers may need to recruit participants before the disease presents with abnormalities or reaches a point of irreversibility. This means enrollment of neonates or infants with identified genotypes, and with varying levels of risk for clinical manifestations and long-term disabilities. This poises both the challenge of designing and executing trials in neonatal populations, as well as the opportunity to have the earliest and potentially most lasting positive impact on people's lives. As such, these challenges and opportunities for the development of these therapies quickly move from a mole hill to a mountain when we consider the vulnerable population of neonates that could be targeted for the evaluation of efficacy and safety of these groundbreaking therapies.

continued on Page 21

With the aim of combining efforts to assess how unmet needs in the development of regenerative therapies within neonatal populations can be addressed through pre-competitive collaboration, Critical Path Institute's (C-Path) International Neonatal Consortium (INC) has formed a dedicated cell and gene therapy initiative.

At the inaugural meeting of this C-Path initiative, in February 2024, stakeholders from academia, industry, neonatal and pediatric nurses, patient advocacy and global regulatory bodies (e.g. the U.S. Food and Drug administration, Health Canada, European Medicines Agency, and Japan's Pharmaceuticals and Medical Devices Agency joined to initiate the identification of tangible unmet needs in the development of regenerative therapies that would require intervention in neonatal populations. A quick export of data from clinicaltrials.gov, presented by Thomas F. Miller, Global Head, Acute, Chronic & Pediatric Disease Nucleus at Bayer Healthcare, LLC, displayed the substantial number of cell and gene-based therapies currently being researched with over 5000 interventional, sponsored trials of which approximately 1000 included enrollment of a pediatric population and over 300 enrolling neonates (see table 1). The indications of neonatal cell or gene-based clinical trials ranged from bronchopulmonary dysplasia, to degenerative, high-mortality disorders like spinal muscular atrophy. The discussion broadened further with review of a 2022 publication within The Pharmacogenomics Journal that outlines the demand for rapid whole-genome sequencing (rWGS) within the pediatric population, the value it has for real-world application compared to standard diagnostic genetic testing of critically ill pediatric patients.[1]

Table 1 clinicaltrials.gov search results

	Emerging Stem Cell Based Therapies	Emerging Gene Based Therapies
Total *Unique Identifiers...*	>9400	>10600
That are *Interventional*	>8200	>7500
And are *Sponsored Trials*	>2300	>2870
And *Enroll Children*	435	494
And *Allow Enrollment of Neonates*	180	164
Example/s	HUCD-Mesenchymal SCs for the Tx of BPD	AAV-based monogenic Dx targets: SMA, DMD, IRDs

Further discussion focused on the benefits for the field of regenerative therapy clinical development that direct-to-pediatric clinical programs can provide. These opportunities are expected to help shape the C-Path cell and gene therapy initiative through actionable deliverables such as public workshop, data-based solutions/tools that can be generated or other actions utilizing real world data and evidence from neonatal populations. Examples of the discussion topics included:

- Rapid advancement in technology (delivery and precision)
- legislation
- regulatory context and incentives
- life cycle strategies focusing on the youngest possible patients
- diagnostic improvements (i.e. rWGS)

continued on Page 22

INC's cell and gene therapy initiative formed to support the acceleration of the development of regenerative therapies, which presents a significant opportunity to address unmet needs across several diseases in the vulnerable neonatal population as genetic disorders are one of the leading causes of illness, hospitalization, and mortality among pediatric populations including neonates2. This exciting class of therapeutics, is ushering in a new era of medical product development which can be life changing for the patients and families affected by the conditions. The pathway to developing new regenerative medicine therapies – particularly for conditions where meaningful disease-modification can be achieved– poses its unique set of challenges and opportunities as most complete clinical symptoms are not always evident in newborns.[2] These include navigating the complexities related to accessing relevant patient populations, an evolving understanding of disease progression, long-term impacts of regenerative medicine therapies, and safety issues linked to delivery mechanisms. Collaborative efforts will be directed towards navigating the intricacies and addressing the unique gaps involved in the development of regenerative therapies—including cell therapies, gene therapies, in-vivo gene editing technologies, and Whole Genome Sequencing (WGS) platforms—for neonates and other pediatric populations. This initiative will highlight the unique challenges and opportunities for pediatric populations, but also focus attention on and share family/caregiver perspectives and experiences. Ensuring all perspectives are considered is a pivotal piece of gathering this group; engaging caregivers will allow all stakeholder groups to understand the importance of building trust, communicating the purpose of treatment/screening, and other implications of this novel therapeutic area.

By integrating patient-level data from diverse sources – including clinical trials, longitudinal studies, patient registries, and real-world data across different rare neonatal diseases – INC along with the initiative members hope to improve study designs, optimize necessary patient sample sizes, and pioneer innovative methods to evaluate these trials.[3] Such integrative approaches can lead to a more refined characterization of rare neonatal diseases, potentially accelerating patient access to new disease treatments through regenerative medicine therapies, advanced diagnostic tools, and personalized medicine approaches.

This component of INC's work in navigating the intricate landscape of gene therapy research and its application to clinical settings while prioritizing safety, efficacy, and ethical considerations links very well to INC's mission. Given the distinctive physiological and developmental needs of neonates, INC is dedicated to developing innovative strategies to address genetic disorders early in life, aiming for treatments or significant improvements in conditions previously devoid of effective solutions. This work includes collaborative research to assess the long-term effects of gene therapies in young patients, the development of specific tools for clinical trials, and efforts to further optimize the efficiency of the regulatory review process. INC also explores new methods for delivering gene therapies to neonates, aiming to address tangible challenges unique to this age group. By promoting cooperation among researchers, healthcare professionals, patient advocacy groups, and regulatory agencies, INC seeks to hasten the development of gene therapies that can significantly impact the health outcomes of newborns.[3]

This is the driving force behind the C-Path's effort in this field. Specifically, the cell and gene therapy initiative is envisioned to provide the opportunity to coalesce knowledge across C-Path consortia that work in indications where regenerative therapies are being developed, for which intervention at the earliest stages of life would be required for the execution of clinical trials. This will also provide a way to maximize the potential of the rapidly evolving field of regenerative medicines for neonates and early childhood which could impact patient outcomes long term.

continued on Page 23

By synergizing and empowering all C-Path consortia with an interest in regenerative therapy development, INC's cell and gene therapy initiative will be poised to seize the opportunities ahead and optimizing the development of these therapies for multiple indications.

C-Path is a nonprofit organization dedicated to improving and streamlining the process of drug development. C-Path achieves tangible, actionable results by fostering collaboration between industry executives and scientists, academic researchers, regulators, and patient groups. To meet this mission, C-Path operates as an independent, public-private partnership with the U.S. Food and Drug Administration (FDA), created under the auspices of the FDA's Critical Path Initiative program in 2005. Since its founding, C-Path has been unique in its ability to develop solutions through open, precompetitive collaboration. C-Path continually seeks to push boundaries and address emerging challenges within the healthcare landscape. Recently, one of its longest-standing collaborations, the International Neonatal Consortium (INC), has embarked on a groundbreaking initiative focused on cell and gene therapy. To further propel C-Path's mission of innovation, one of the longest established collaborations, the International Neonatal Consortium, has recently launched a pioneering cell and gene therapy initiative.

For questions or additional information related to INC and the cell and gene therapy initiative, please contact INC at incinfo@c-path.org or visit International Neonatal Consortium (c-path.org).

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1. Diaby, V., Babcock, A., Huang, Y. et al. Real-world economic evaluation of prospective rapid whole-genome sequencing compared to a matched retrospective cohort of critically ill pediatric patients in the United States. Pharmacogenomics J 22, 223–229 (2022). https://doi.org/10.1038/s41397-022-00277-5
2. Ouyang X, Zhang Y, Zhang L, et al., Clinical Utility of Rapid Exome Sequencing Combined with Mitochondrial DNA Sequencing in Critically Ill Pediatric Patients with Suspected Genetic Disorders. Front Genet.12:725259. (2021)
3. Critical Path Institute. International Neonatal Consortium. Available at: https://c-path.org/programs/inc/. (2024)

Empowering Innovators and Accelerating Pediatric Solutions: Children's Mercy's Center for Pediatric Innovation and PedsMrkt Marketplace

*Krista Nelson, BS, and Sallie Guezuraga, MBA****

At Children's Mercy Kansas City, the Center for Pediatric Innovation has a unique model to bring innovations to life. Successful innovation is rooted in solving for needs by creating new solutions that bring value and fit into patient and family flow of life and provider clinical flow. The Center's model empowers any employee or clinical champion to share their ideas and bring their expertise, while the Center completes the value stream with complementary skillsets to create market viable solutions. The Center brings a human-centered design and a needs-based approach to drive solution development and develop ideas from concept to commercialization. With a full pipeline of market viable solutions, the Center was challenged to find a sustainable way to get solutions to the fragmented pediatric market. So, the Center applied these same innovation principles and created a pediatric marketplace, called PedsMrkt.

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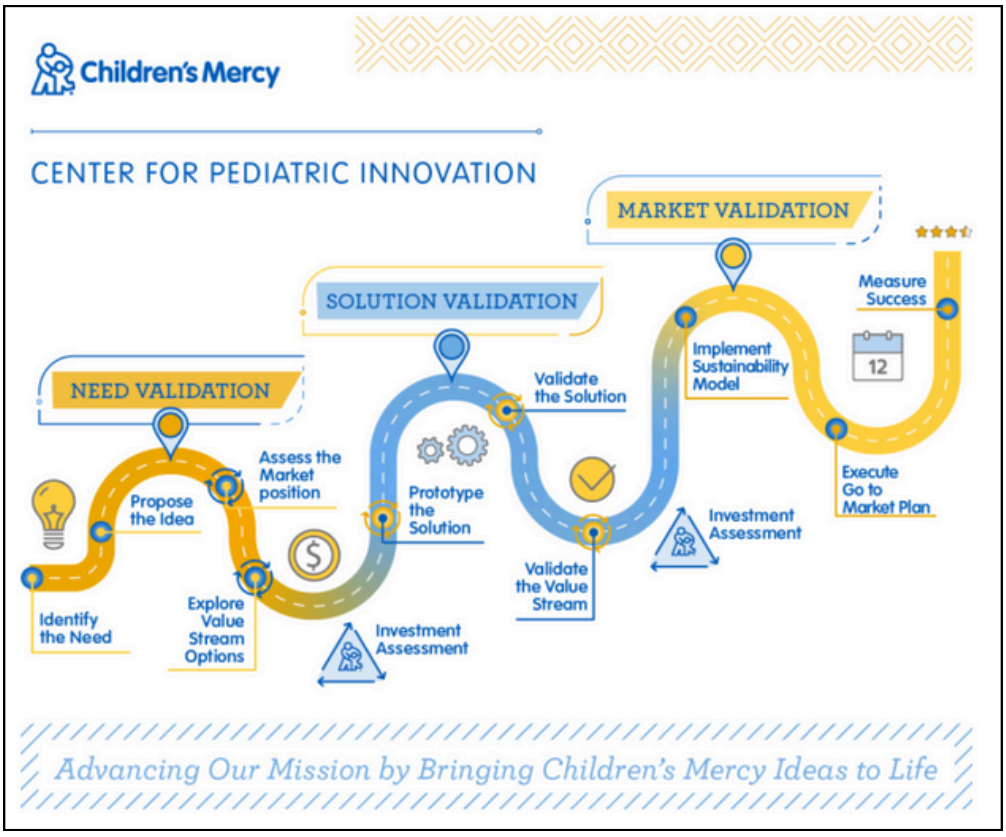


The Center was established over 10 years ago when it was prioritized as part the Children's Mercy strategic plan. The Center's goals include providing meaningful impact on employee engagement and job satisfaction by empowering them to make a difference in patients' lives as employee innovators. This engagement would ultimately serve to advance Children's Mercy's mission, build reputation, and create new sustainability and commercialization models through intrapreneurship.

To date, over 300 employees have submitted ideas to the Center. An additional 120 employees have pitched ideas during the annual SPARK Bash (Sparkling Pediatric Advancement and Revolutionizing Kids' Health), where innovators' ideas are voted on by their peers to win seed funding for development of their ideas. Here are some examples of innovations developed over the years with Children's Mercy clinical champions:

- PedsGuide is a mobile application that helps health care providers and emergency service personnel with step-by-step interactive clinical decision support for children facing acute illness. The app has over 47,000 downloads from across the country.
- MyHeartArt allows anyone on the care team to quickly produce an anatomically correct, artist-quality rendering of a patient's specific congenital heart defect as well as surgical repairs as a patient progresses through care.
- HearPlay is an iPad application designed to get more accurate and efficient hearing assessments for children 2 to 6 years old and those with developmental delays, enabling a single audiologist to perform the tests. It is used in over 25 audiology centers.
- Gripper Tool holds a hub and safely facilitates the release of an adapter, Luer-Lok™, ENFit® connector, needleless connector, and/or other connectors used with catheters or other medical devices that have become difficult to disconnect. Licensing discussions are currently under way.

continued on Page 25

Going to market with pediatric solutions is exceptionally challenging. There are many unique barriers which currently impede pediatric innovations:

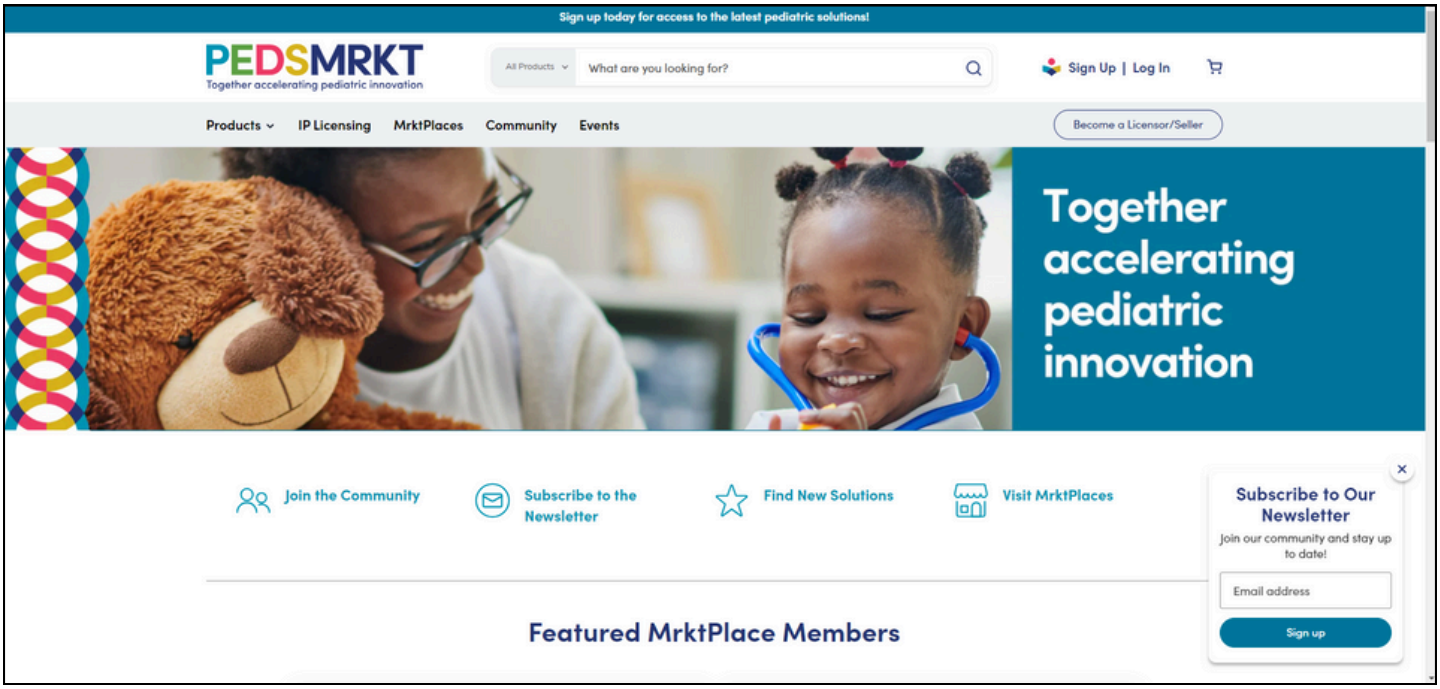
Make-Do Approach: With the pediatric market not being viewed to be as profitable as the adult market, even though children represent approximately 22% of the national population[1], they have been historically underrepresented in funding innovation in care delivery and medical device development. Devices, some decades old, and medicines created for adults are often used off-label and providers try to best adapt them for kids. Kids are not mini-adults, and often this can lead to suboptimal care.

Higher Solution Development Costs: Enrolling the required number of patients for research studies can take longer due to the smaller populations, developmental variables, and ethical considerations. Additionally, these dynamics can also increase the cost of market validation and regulatory processes.

Commercialization Challenges: When hospitals or startups create a new pediatric device or solution, larger manufacturers and distributors may not be interested due to smaller market sizes. As a result, they are left on their own to find collaborators, build awareness and market their solutions. In addition to, navigating the complicated purchasing systems that are different at every hospital and require individual contacts within each pediatric institution.

To address these challenges, the Center began talking to peers at pediatric institutions, various start-ups, and pediatric innovators across the globe. Throughout this dialog, they learned others had similar challenges - confirming the collective assessment that many discoveries, intellectual property, and solutions were stuck without an effective go-to-market strategy and infrastructure; and therefore, did not reach the patients who could benefit from them. It also reinforced the pediatric market is not big enough to support duplicative innovations to meet the same niche needs.

With a desire to solve for these needs to enable collaboration across the pediatric eco-system and build awareness of all pediatric solutions, the Center launched a first-of-its-kind pediatric online marketplace, called PedsMrkt. PedsMarket, LLC was spun out as a for-profit subsidiary of Children's Mercy.



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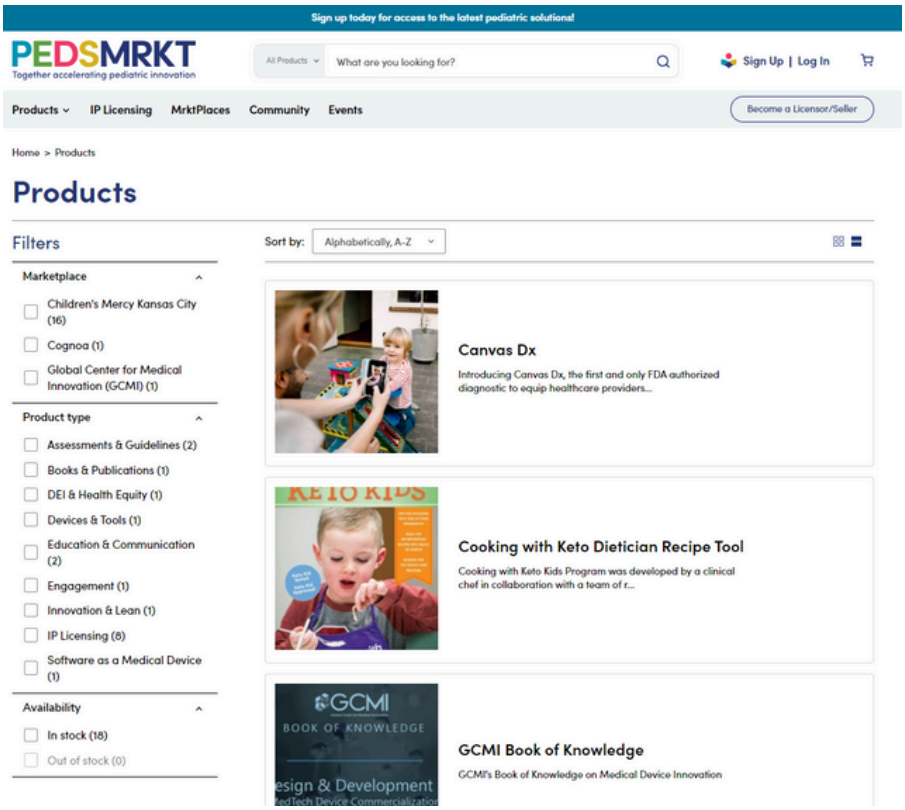
PedsMrkt invites the following participants of the pediatric eco-system to engage:

- Pediatric hospitals
- Pediatric divisions in adult hospitals
- Pediatric healthcare associations
- Start-ups and other pediatric innovators
- Tech companies & device manufacturers
- Device consortiums
- Medical supply companies
- Vendors & consultants
- Investors

These participants can engage as browsers/buyers, sellers/licensors and/or marketing partners, either for free as a browser/buyer or as a paid member to bring awareness, scale and disseminate their innovations or services. As a paid member, specifically for pediatric hospitals, it provides the opportunity to 1) highlight and bring awareness to licensable assets as a one-stop-shop for potential entrepreneurs or manufacturers, 2) use the eCommerce platform to receive payments for solutions, 3) promote market-ready solutions by linking to an existing website and 4) to share free downloadable resources with other institutions. For example, Children's Mercy is currently selling two solutions via credit card, has several free resources available to download, is linking to multiple digital solutions (directly to the app store or to a website landing page), and has eight licensable assets as product listings in the marketplace.

These same member benefits are also available for any of the participants in the list above to promote their solutions, portfolios or services.



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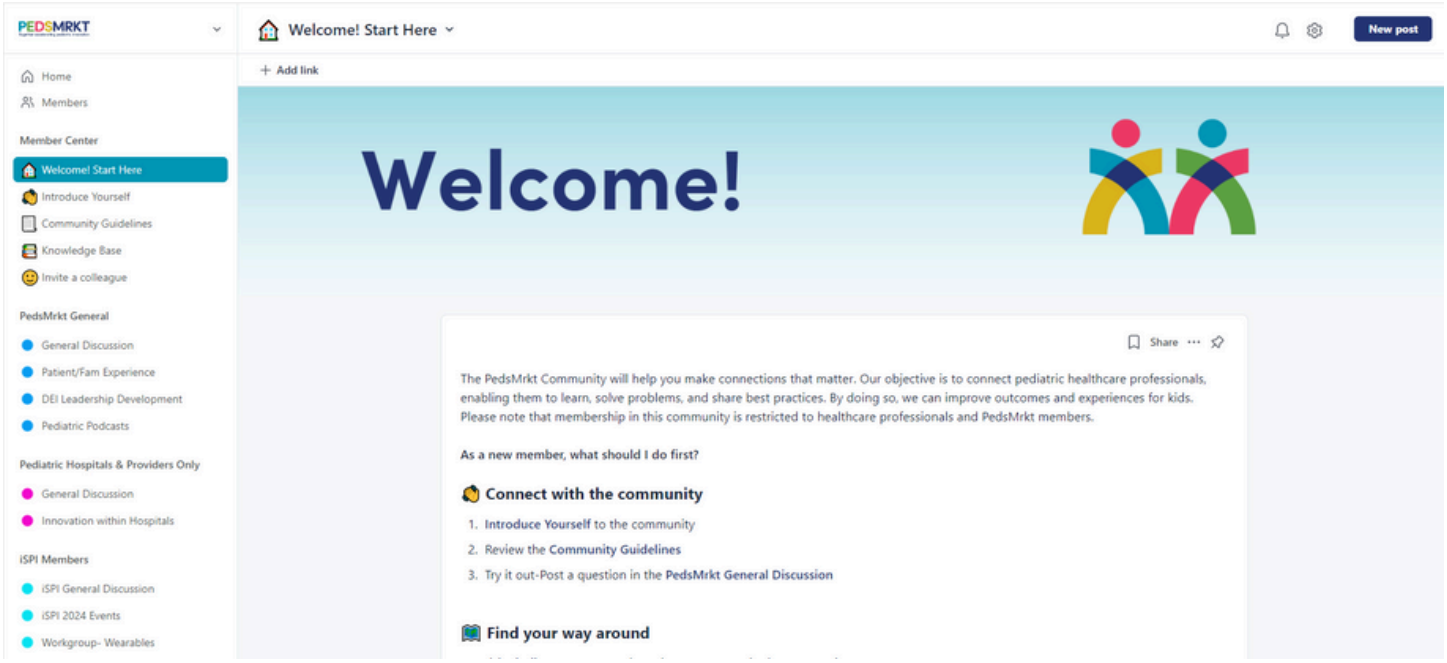
Another feature available for all pediatric providers, institutions, and paid members of PedsMrkt is to engage in discussions among pediatrics in the new PedsMrkt Community. The PedsMrkt Community platform was created to redefine how the pediatric industry collaborates This is an opportunity for specialty areas, innovation centers, researchers and other insight gathering groups to use this community to replace existing emailing and ListServ's, for example, that are happening today. This option is available with a private or public community option.



As a result of launching PedsMrkt, the Children's Mercy team was honored by the International Society of Pediatric Innovation with their "Game Changer Award."

Within the first few months of launching, PedsMrkt has over 620 LinkedIn followers, representing the diversity of the ecosystem. This shows the value proposition of PedsMrkt continues to resonate across the industry as engagement in the site continues to grow.

Dawn Wolff, Vice President, Strategy, Innovation, and Partnerships, Children's Mercy Kansas City and Vice President, PedsMarket, LLC states, "Kids deserve all of us coming together for their health and wellbeing. To be successful, we need to connect with other innovators. PedsMarket has the potential to transform pediatric healthcare innovation. Join this movement to accelerate pediatric innovation together."
To learn more about PedsMrkt, please reach out to info@pedsmrkt.com.

References:

1. https://www.census.gov/library/visualizations/interactive/exploring-age-groups-in-the-2020-census.html

A Message from the Membership Committee

Our Section continues to grow!

Who Can Join?
1. AAP Members

Membership in the section is open to AAP Fellows, Specialty Fellows, Candidate Members, Post Residency Training Members, Honorary Fellows, Emeritus Fellows, and Corresponding Fellows with an interest in advances in therapeutics and technology. There is no fee for AAP members.

2. SOATT Affiliate Members

Affiliates are those who are not eligible for membership in the AAP and hold a Masters degree or Doctorate (or equivalent) in pharmacy or other health science concentration. Affiliates must submit an application (see "How to Join" below) and have a signed letter of support from an AAP fellow in good standing. There is a $40 annual fee for section affiliate members.

How to Join?
If you are already a member of the AAP and would like to become a SOATT member, join online by:

- Going to Member Center of the AAP website and use your AAP login and password.
- Click on "Join a Section or Council" under Member Community.
- Choose "Advances in Therapeutics and Technology", answer a few questions, and click "Submit".

Membership applications can be found at:
https://www.aap.org/en/membership-application/join-aap/

If you have any questions about membership, please contact Eleni Victoria at evictoria@aap.org

We want to hear from you!

Submit your article today!

We welcome contributions to the newsletter on any topic of interest to the pediatric community.

Please submit your idea or article to:

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Byron Alex, MD, MPH, FAAP (Therapeutics Co-Editor): btalex@gmail.com

(Ryan) Brandon Hunter, MD, FAAP (Devices Co-Editor): rxhunter@texaschildren.org

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(August 2023 to May 2024)

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continued on Page 30

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continued on Page 31

Welcome New SOATT Members *continued from Page 30*

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Announcements from the AAP

Have You Visited SOATT's Collaboration Web Page?
https://collaborate.aap.org/SOATT
All of the members-only documents are on the collaboration page. Check it out!

Basic information about SOATT is on AAP.ORG
https://www.aap.org/SOATT

See AAP's Parent Brochure on Pediatric Clinical Trials
(Written by SOATT)
https://www.healthychildren.org/English/health-issues/conditions/treatments/Pages/Should-My-Child-Join-a-Clinical-Trial.aspx

Pediatrics Open Science: The AAP newest and first gold open access journal!

We are pleased to announce *Pediatrics Open Science*, the American Academy of Pediatrics' newest and first gold open access journal. The journal's goal is to improve the health of children and families by providing free access to pediatric research perspectives and findings from around the world. *Pediatrics* will continue to publish AAP policy statements, clinical and technical reports, and other high-quality research papers. Pediatrics will remain a hybrid publication, with both paid and open gold open access articles.

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Editor-in-Chief John Patrick T. Co, MD, MPH, MBA, FAAP, and a dedicated team of associate editors will oversee the journal, ensuring that all research undergoes a rigorous peer review process. This commitment to publishing excellence is essential for maintaining credibility and trust within and outside of the scientific community. The new editorial board is in the process of defining the scope of topics they wish to publish in the journal, including general pediatric research. Articles will eventually be published on a weekly rolling basis and the journal will accept a limited number of open access papers annually.

Manuscripts can be submitted at https://submit-pedsos.aappublications.org/; the journal's submission system opened on April 29, 2024.

Additional information is available at publications.aap.org/pediatricsopenscience. We are planning to publish our first set of articles in the fall of 2024. If you have any questions about the journal, please contact pedsos@aap.org

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