



Reflections from the Chair



“SOATT Networking to Spur Innovation”

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One of the most common requests I receive from Section members and this came out in our member survey is for opportunities to network with other members of the Section. SOATT is filled with forward-thinking innovators who have ideas to improve the lives of children (and this came out in our member survey). But taking an idea from concept to impact rarely can be done alone. Our Section consists of more than a thousand pediatricians and pediatric subspecialists and specialists across the innovation spectrum. Some with years of experience, some with bold fresh ideas, and some with both! We have members who are researchers, regulators, work for government or industry (tech, devices and pharma), and funders. So, it is no wonder that members with ideas seek out other members who bring another piece of the puzzle to get an idea off the ground.

In an effort to promote networking opportunities and to increase knowledge of the issues facing pediatric device developers (which includes technology), SOATT sponsored a panel discussion at the 2022 NCE in Anaheim, which was followed by a mid-day networking reception. Both events achieved their goals and many attendees mentioned to me how valuable this was and that we should do it again at the 2023 NCE. So SOATT will be sponsoring a similar panel and networking reception at the NCE in Washington DC. If you are planning to attend NCE, please join the SOATT H program, meet other members of the Section, and maybe meet someone who can help you bring your idea to life! We will post information about the SOATT NCE events on the Section mailing list when the NCE schedule becomes available.

In addition to networking events at NCE, we are planning a SOATT member directory which will list SOATT members' areas of expertise and interests, along with whether they are willing to mentor others and/or give advice as it relates to innovation in therapeutics, devices and technology. Participation in the directory will be entirely voluntary. If any member of the Section is interested in working with the Section Executive Committee in helping put this directory together, please let me know at crizzo624@gmail.com. This would be a good project for a few young pediatricians who want to get involved in the Section and the Academy.

I also encourage members of the Section to submit abstracts for poster presentations at the NCE. For the first time that I can remember, all of the posters were in one location which made it much easier for attendees to locate posters of interest. If your research relates to an innovation in pediatrics, please consider submitting your NCE abstract under SOATT. Details on abstract submission will also be posted on the Section mailing list when details become available.

Speaking of posters, I saw something tremendous at the SOATT poster session in Anaheim. Paul Kent MD presented a poster titled “First Report of Naxitamab Response for Brain Metastasis in Refractory High-Risk Neuroblastoma”. The poster described use in an adolescent patient. The poster included a photo of the patient and she was the lead author! While the treatment did result in improvement, she did not survive a bout of sepsis nearly a year later. Not only did I think including her as an author was a great idea, but Dr Kent tells me the patient's family was very surprised and honored to hear about it and it was a meaningful legacy for them. Perhaps we should more often consider honoring our patients and families in this and other ways when possible.

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And speaking of patients, I want to mention iCAN. The International Children's Advisory Network. iCAN's mission is "To foster greater global understanding about the importance of the pediatric patient and caregiver voice in healthcare, clinical trials, and research." Your patients, especially those with chronic conditions who want to advocate for other children in the health care system, can join a chapter and/or attend the national conference being held in Southern California July 10-14, 2023. More information can be found at www.icanresearch.org.

Finally, while many members of our Section work in industry or government, the majority of our members are clinicians or clinician/researchers who recently went through what has been described as Pediatrics' pandemic. I am talking about the surge in respiratory viruses that started in the late summer and inundated offices, emergency departments, pediatric wards, and PICUs. This occurred while health care workers were still weary from the SARS-CoV-2 pandemic, dealing with staff and bed shortages, and facing scared families who usually don't understand why often nothing more than supportive care is available. My hat goes off to you and the rest of the staff. As innovators, let us all think not only of interventions that can help individual patients, but also of those that can improve our clinician's and staff experience managing these children.

The AAP is the American Academy of Pediatrics, not the American Academy of Pediatricians. And while that has served our mission well, we should not forget that we need healthy pediatricians to ensure healthy children. Our ideas as innovators should include those that also improve the work experience of pediatricians, pediatric specialists, and the staff. Burn out is real and if we don't improve things, we won't attract young people to the health care field which will only exacerbate the problem.

Thank you for all you do – each and every day.

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From the Editor's Desk:

“A Note from a New Co-Editor”

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Welcome to the Winter 2022 edition of the AAP SOATT newsletter!

I am pleased to introduce this latest edition of the newsletter featuring topics on both therapeutics and devices. As one of the recently added co-editors of this newsletter (along with Brandon Hunter), I am finding that the role of this newsletter is to respond to the interests of our community by sharing a relevant collection of content. This is not dissimilar from social media platforms like LinkedIn or Reddit, though what you will find here has distinctive qualities. Nested within our AAP section, we all share a passion for pediatric health and have the potential to gather in-person with colleagues at NCE. In addition, you will find this newsletter has more of a “long-form” approach to content compared to what is commonly seen on social media.

I am pleased to introduce this latest edition of the newsletter featuring topics on both therapeutics and devices. As one of the recently added co-editors (along with Brandon Hunter), I am finding that the role of this newsletter is to respond to the interests of our community by sharing a relevant collection of content.

We hope that you enjoy reading this edition of the newsletter, and please share it with a colleague, patient, or friend. We welcome all suggestions for articles, and especially those related to innovations in therapeutics and technology. This is an avenue of communication for our Section, and for those who share the passion of caring for children and improving our care for children.

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. 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>

National Capital Consortium for Pediatric Device Innovation

(Children's National Health System / University of Maryland)

innovate4kids.org

Pennsylvania Pediatric Medical Device Consortium

(Children's Hospital of Philadelphia / University of Pennsylvania / Drexel University / University of Pittsburgh)

ppdc.research.chop.edu

Southwest National Pediatric Device Innovation Consortium

(Texas Children's Hospital and Baylor College of Medicine / Texas A&M / Rice / Univ. of Houston / Fannin Innovation Studio)

SWPDC.org

West Coast Consortium for Technology and Innovation in Pediatrics

(Children's Hospital Los Angeles / University of Southern California)

www.westcoastctip.org

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

Fall 2022 SWPDC and AAP Section on Advances in Therapeutics and Technology (SOATT) Pediatric Device Prizes

Chester J. Koh, MD, FACS, FAAP and Kara Toman, MPH
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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 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. Thanks to Chris Rizzo, MD, FAAP, SOATT Chair, and Jackie Burke, SOATT Section Manager, 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 2022 are:

\$25,000 – Luminoah Inc - Hill Johnson (Charlottesville, VA)

The enLumin from Luminoah is a portable, intuitive, and connected device for enteral nutrition in pediatric patients that require tube feeding. The system includes 3 main components: the enLumin Enteral Feeding Pump, the enLumin Daily Administration Set, and the enLumin Smartphone Application.

\$25,000 – Pyramex - Xina Quan (Cupertino, California)

The Boppli is a non-invasive wearable device for neonatal ICU patients for continuous blood pressure monitoring with minimal skin contact and serves as an alternative to arterial catheters and inflatable cuffs. Clinical studies in pediatric patients are ongoing.

\$10,000 (in kind support) – Glimpse Diagnostics LLC – Courtney Hill, MD (Arden Hills, MN)

Glimpse is a combined hardware and software solution for enabling telehealth treatment at home for pediatric ear infections that accommodates anatomy and specific needs for eardrum visualization.

We congratulate the winners of the Fall 2022 awards! The next award cycle will take place in Fall 2023, and we encourage all pediatric device innovators in the AAP SOATT to apply.

We also wish to thank our SWPDC staff (Christine Luk, Kathryn Garn, and Dr. R. Brandon Hunter at TCH / BCM) 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 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 Fannin Innovation Studio. 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 nondilutive, “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.

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Recap of the SOATT Program at the 2022 AAP NCE (Anaheim, California)

Chester J. Koh, MD, FACS, FAAP

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and the Southwest National Pediatric Device Innovation Consortium (SWPDC.org)

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"From Gadgetologist to Entrepreneur" served as the theme of this year's annual SOATT program at the 2022 AAP NCE in Anaheim, California on Monday 10/10/2022. The engaging program was assembled by Dr. Christina Bucci-Rechtweg, MD, chair of the SOATT Educational Programming and hosted by SOATT Chair, Dr. Chris Rizzo, with a moderated panel discussion led by Dr. Vasum Peiris (FDA) and Dr. Chester Koh (Texas Children's Hospital / Baylor College of Medicine) with panelists, Dr. Kolaleh Eskandarian (Children's National Medical Center) and Dr. Juan Espinoza (Children's Hospital Los Angeles / USC) and Dr. Andrey Ostrovsky. The discussion centered on the challenges that affect pediatric device development as well as the resources currently available for pediatricians and pediatric specialists such as the FDA Pediatric Device Consortia program and especially if they are interested in becoming a gadgetologist or even an entrepreneur.

This year's winner of the SOATT Award for Pediatric Innovation is Dr. Raymond Sturner, a developmental – behavioral pediatrician who shared the history of the Comprehensive Health and Decision Information System (CHADIS), a web-based Clinical Process Support System that is now used in 48 states and 10 countries, including for early screening of autism.

The awards for the top three SOATT research abstracts were also acknowledged at the end of the session, and a list of the abstract winners and the other submitted abstracts are listed in this newsletter edition.

After the conclusion of the SOATT program, the attendees were able to meet others in an informal setting during the 1st ever Pediatric Innovations Networking event. After enjoying the refreshments and hors d'oeuvres, attendees were able to view the posters at the SOATT Poster Session afterwards.

We look forward to seeing you at next year's SOATT program at the 2023 AAP NCE in Washington DC!



**From left: Chester Koh (moderator), Vasum Peiris (moderator) Chris Rizzo (Section Chair)
Juan Espinoza (faculty) and Kolaleh Eskandarian (faculty)**

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ACCEPTED ABSTRACTS 2022

These abstracts were on display at the AAP National Conference in Anaheim, CA. The abstracts in yellow were chosen as the top papers.

Submission Title	Submission Type
A Novel Method to Identify Streptococcus Pharyngitis Using Smartphone Images and Artificial Intelligence	Original Research
A single institution series of prolonged response with combination check-point inhibitor / tyrosine kinase inhibitors for relapsed/refractory sarcoma	Original Research
A Single-Period, Single-Dose Study of the Pharmacokinetics of Epinephrine After Administration of Intranasal ARS-1 to Pediatric Subjects with Systemic Allergic Reaction	Original Research
Analysis of the Number of Research Experienced Pediatric Clinical Trial Investigators in the United States: A Critical Need and a Lot of Room for Improvement	Original Research
Baseline Demographics and Disease Characteristics of Adolescent and Adult Patients With Eosinophilic Esophagitis From Part B of the 3-Part, Randomized, Placebo-Controlled, Phase 3 TREET Study	Original Research
Comparative study of H.pylori eradication rates of high and frequent dose of Omeprazole and Amoxicillin dual therapy versus standard triple therapy in children	Original Research
Creating a Streamlined Process for the Building of Myoelectric Pediatric Prostheses	Quality Improvement Project
Diaphragm Pacing in an Infant with Respiratory Failure Secondary to Unilateral Diaphragm Paresis: A Promising Intervention	Case Report
Dupilumab Efficacy in Children With Moderate-to-Severe Type 2 Asthma Analyzed by High- or Medium-Dose of Inhaled Corticosteroids at Baseline: LIBERTY ASTHMA VOYAGE study	Original Research
Dupilumab Improves Health-Related Quality of Life in Children Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis and Children Aged 6 to 11 Years with Severe Atopic Dermatitis and Their Caregivers	Original Research
Dupilumab Treatment Improves Sleep Quality in Children Aged 6 Months to 5 Years with Moderate-to-Severe Atopic Dermatitis and Their Caregivers	Original Research
Dupilumab Treatment Is Not Associated With an Increased Overall Risk of Infections in Patients Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis	Original Research
Dupilumab Treatment Shows Rapid and Consistent Improvement in Atopic Dermatitis in All Anatomical Regions in Patients Aged 6 Months To 5 Years	Original Research
Efficacy and safety of tralokinumab in adolescents with moderate-to-severe atopic dermatitis: results of the phase 3 ECZTRA 6 trial	Original Research
Efficacy and safety of trofinetide for the treatment of girls and young women with Rett syndrome: results from the randomized, double-blind, placebo-controlled, pivotal, phase 3 LAVENDER study	Original Research
Evaluation and comparison of red cell distribution width (RDW) values in patient with autoimmune hypothyroidism and healthy pediatric population: Retrospective Case Control Study	Original Research
Exploring the real world performance of an artificial intelligence-based diagnosis aid for autism: An aggregate and de-identified analysis of early Canvas Dx prescription and output data post-market authorization	Original Research
First Report of Naxitamab Response for Brain Metastasis in Refractory High Risk Neuroblastoma	Case Report
Identifying Targets for Innovation: A Thematic Analysis of Bedwetting Alarm Reviews	Quality Improvement Project
Impact of Patient Demographic and Disease Characteristics on the Efficacy of Dupilumab in Children With Asthma in the VOYAGE Study	Original Research
Improved Growth in Children with Acid Sphingomyelinase Deficiency Treated with Olipudase Alfa Enzyme Replacement Therapy	Original Research

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In Vitro Antibiotic Resistance Among Bacterial Pathogens from Pediatric Patients with Eye Infections: 13-Year Results from the ARMOR Study	Original Research
Injectable Hydrogel for Cardiac Regeneration	Original Research
Medical Trauma of Parent and Child Caused by Clinical Trial Participation: Insights of a Parent with a Child Clinical Trial Participant and the Trauma Caused From the Decision Making Process and Participation in Multiple Trials	Case Report
Nivolumab and Lenvatinib Immunochemotherapy in 20 Children and Young Adults with Unresectable or Metastatic Fibrolamellar Carcinoma	Original Research
Outcomes and Impact of the 2013-2018 FDA Pediatric Device Consortia Funding Cycle	Original Research
Parental Perceptions of the HPV Vaccine for Prevention of Anogenital and Oropharyngeal Cancers: a Qualitative Study	Original Research
Physician preferences regarding pediatric combination vaccines in the United States	Original Research
Recommended First Tier Genetic Testing for Patients with Neurodevelopmental Disorders has Diagnostic Utility	Original Research
Returning Individual Trial Results – nice idea, major challenges	Quality Improvement Project
Serdexmethylphenidate/dexmethylphenidate (SDX/d-MPH) Optimized Dose Levels and Effects on Attention-Deficit/Hyperactivity Disorder-Rating Scale-5 (ADHD-RS-5) Response Rates in Children With ADHD	Original Research
Study Design of a Randomized, Double-Blind, Placebo-Controlled Study to Investigate the Efficacy and Safety of Dupilumab in Children Aged 1–11 Years, With Active Eosinophilic Esophagitis	Original Research
Summary of Baloxavir Marboxil Safety and Efficacy Outcomes in Pediatric Patients Aged 5-11 Years: Data From 3 Studies	Original Research
The Effect of Allergen Sensitization Status On Dupilumab Efficacy In VOYAGE Pediatric Patients With Uncontrolled, Moderate-to-Severe Type 2 Inflammatory Asthma	Original Research
The effectiveness of the probiotic L.rhamnosus GG in Pediatric Atopic Dermatitis: results from the ProPAD trial	Original Research
The Sickie Cell Pain Action Plan: A low health literacy, pictographic tool to enhance self-management and guideline concordance	Quality Improvement Project
Tralokinumab Treatment Substantially Improves Patient-Reported Outcomes in Adolescents with Moderate-to-Severe Atopic Dermatitis at 16 Weeks	Original Research
Transcutaneous Bilirubin Diagnostics and Newborn Racial Disparities	Original Research

Thank you to Mitchell Goldstein, MD, FAAP for chairing the competition and to all the judges!

Be Informed! Get Involved!

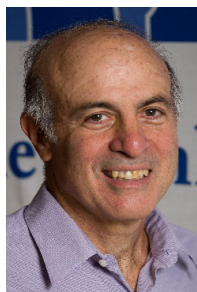
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email Jackie Burke at jburke@aap.org**

Congratulations to Raymond Sturner, MD, FAAP

2022 Section on Advances in Therapeutics & Technology Award for Pediatric Innovation Winner!



Excerpt from nomination letter:

I am writing to nominate Raymond Sturner, MD, FAAP for the AAP SOATT award as an outstanding pediatrician actively engaged in bringing innovation to improve the health and well-being of infants, children, adolescents and young adults, especially in Maryland. Dr. Sturner is a developmental-behavioral pediatrician and longtime member of the AAP, and co-creator of the Comprehensive Health and Decision Information System (CHADIS), a web-based Clinical Process Support System, now used in 48 states and 10 countries.

Dr. Sturner and his colleagues have donated licenses to pediatric and FQHC providers across Maryland to improve screening, decision support, patient education and resource access. CHADIS was the basis of early autism screening for the Dept. of Education and in the past few years and became a mechanism for easier administration of the M-CHAT Follow Up and direct referral of children to Montgomery County Infants and Toddlers. He co-developed a module for, not only screening for Social Determinants of Health that put the child at risk for maltreatment such as intimate partner violence, but also facilitating a motivational interview by the provider with the parent to accept help. CHADIS then automatically provides local resource listings for the family in individual private web pages. This mechanism is now part of an SDoH project funded by the Community Health Resources Commission along with the Open Table volunteer support system and Dr. Joseph Weidner. Most recently Dr. Sturner co-created a Youth Health Module in CHADIS that screens for substance use with an interactive educational graphic component and assists clinicians in a motivational interview to prevent or reduce substance use in Maryland and elsewhere. A parallel module screens for youth depression and suicidal ideation and assists providers in implementing GLAD-PC, NIMH and AAP guidelines for both, also directing strength building resources to the youth and a chatbot to provide cognitive behavior therapy for depression.

As Director, Dr. Sturner developed and earned credentials for the Center for Promotion of Child Development through Primary Care as the only portfolio sponsor of the American Board of Medical Specialties to provide physicians Part 4 Maintenance of Certification credits for Quality Improvement efforts in their own practices.



The CHADIS innovations Dr. Sturner developed in Maryland are now a SaaS in use in 48 states and 10 countries by >2 million patients per year to improve evidence-based care. The screening saves money and time for screening and the resulting billing to insurance generates 10-15x ROI to the provider, making a sustainable process.

Meet CobiCure, where success in pediatric innovation is measured by impact, not profit

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In March of 2020 Americans became self-appointed experts in health policy overnight. From boardrooms to kitchen tables, we were debating the nuance of how to ensure safe, scientifically sound, ethical approval of novel vaccines, whether children should qualify as disease vectors, differences in childhood immunity versus adult, and even the intricacies of how to solve critical failures in infant formula

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supply chains and state-sponsored reimbursement. Pediatrics was suddenly central to each conversation. But was it a momentary blip, or will the practice undergo a tectonic shift before our eyes?

At CobiCure we believe that by improving the way that pediatric medical technologies are funded and commercialized, we can ensure that shifts in the market benefit the practice of medicine for the long term.

CobiCure was launched in June by the Advantium Health Network, a philanthropic organization launched by Deerfield Management and the Deerfield Foundation. With CobiCure, Advantium set out to resolve one of the most vexing challenges in healthcare today: how to make advanced, patient-specific technology readily available to pediatricians, regardless of the regulatory and funding hurdles. While pediatricians are overwhelmingly driven to help children grow up as healthy as possible, available medical technologies often fall short. The profit-based business model in the pediatric device market is inefficient, unlikely to change, and it all-too-often fails to satisfy the scale required for scientific rigor and independent regulatory approval.

Only 24% of life-saving medical devices recently approved by the FDA have a pediatric indication, most of those for older children. A deficit of available technology leaves pediatricians and pediatric surgeons with no choice but to modify adult devices to treat child patients off-label, without supporting efficacy data, and regulated by expanded access or compassionate-use exceptions.

The regulatory and technological challenges to this problem are well-known. The creation of the [Pediatric Device Consortium](#) is a promising step towards improving regulatory flexibility, reducing R&D barriers, and helping bring down the cost of clinical trials for new pediatric medical devices.

Baseline funding for the commercialization path is equally challenging. Investment dollars supporting pediatric innovation is staggeringly low. Even federal spending in pediatrics is projected to decline from more than 9 percent of all federal outlays last year to 6.4 percent over the next decade.

Not surprisingly, established medical technology companies shy away from shouldering the huge cost of bringing a new product to market when annual sales are unlikely to reach \$100 million. Upstream it's the same story: investors are unwilling to risk a negative return investing in R&D that seems unlikely to attract later-stage commercialization partners.

Philanthropy is often tapped to help bridge these development gaps, and pediatrics has no shortage of important philanthropic partners. However, charitable giving is subject to wide swings in availability and can't provide the kind of sustainable certainty required to move an innovation from bench to bedside. Public and private grants can be more reliable, but such funding is typically aimed at discovery, not the necessary next steps to reach commercialization.

CobiCure is on a mission to break through these challenges with a new regenerative funding model that measures success by patient impact, not profits, when leveraging self-sustaining, revolving philanthropic dollars to accelerate pediatric innovations to market. CobiCure is also leveraging the resources at Deerfield Management to improve the chances of success.

We are a not-for-profit organization that approaches our mission with the nimbleness, resources, and expectations of a venture investor. We leverage philanthropic dollars as a catalyst to attract additional investment. We provide expertise to help overcome technological and regulatory challenges. We advance device development to attract commercialization partners, and we intend to reinvest revenue into new initiatives, sustaining our efforts over the long term.

We have secured an initial \$10 million in funding to support initial operations with additional funding under development. Our proposed model is three-prong. 1) We license, sell and innovate approved pediatric technologies to provide a revenue stream that will sustain innovation. 2) We collaborate with partners like Deerfield to identify appropriate medical technologies to license. 3) We provide investments with access to state-of-the-art resources at a leading New York City's healthcare innovation campus, Cure, and enhanced development opportunities with partner Coridea, a medical device incubator specializing in cardiac, pulmonary, renal, and neurology conditions.

Our initial focus is on improving pediatric cardiovascular conditions, including interventional cardiology, cardiac surgery, and associated critical care, investing in a device to treat functional single ventricle (FSV) disorder.

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FSV affects the lower chamber of the heart, resulting in drastically shortened lifespans. It is rare - around 2,000 patients are born with FSV each year. But despite how devastating the condition can be, this small patient size means scarce funding to develop treatment technologies.

To address this, we partnered with Transmural Systems, a clinical stage medical device company leading innovation in structural heart therapies, to develop innovative FSV treatments. Licensing existing Transmural technology, CobiCure has committed funding and expertise to hopefully develop it through FDA approval and into the market.

This commitment can't be met in a bubble. As a new organization, CobiCure is actively collaborating with leading experts like those in the FDA Pediatric Device Consortia to help identify promising technologies for deal flow, serve in scientific and clinical advisory functions, and site potential clinical trials. With collaborations like these comes the opportunity to extend our reach by convening thought leaders from across the pediatric medtech landscape to address real change in the pediatric healthcare market.

We will be hosting our inaugural Pediatric MedTech Innovation Summit on November 10, 2022 at Cure in New York City. Representatives from the FDA and National Institutes of Health, along with venture capitalists, key opinion leaders and philanthropists will convene to collectively address these challenges in the pediatric medical technology market.

Profit may be one of humanity's strongest motivators, but it can't be the only one. All too often it falls short of achieving healthier, longer lives for all patients. It is time for new models motivated by altruism, compassion, problem-solving and intellectual curiosity, without sacrificing long term fiscal sustainability. It is time for enduring solutions to ensure our children's health does not fall short.

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1. https://www.fda.gov/media/128659/download?utm_campaign=2019-07-10*20CDRH*20New&utm_medium=email&utm_source=Eloqua
2. <https://www.statnews.com/2021/02/11/medical-devices-children-fast-tracking-innovation/>
3. <https://www.urban.org/research/publication/kids-share-2022-report-federal-expenditures>

Pediatric Device Spotlight - Rhaeos

Wearable Diagnostics in Hydrocephalus

A New Class of Noninvasive Devices That Aims to Significantly Improve Hydrocephalus Care

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The age-old adage that *luck is what happens when opportunity meets preparedness* came true in 2018 when a world-renowned expert in wearable sensors had a chance meeting with a neurosurgeon during grand rounds. The result is poised to revolutionize the care of children diagnosed with a life altering chronic neurological condition.

For decades, surgical implantation of a shunt has been the mainstay treatment of hydrocephalus, a neurological condition in which excess fluid surrounds the brain. This treatment is the most common brain surgery performed in the US and the eighth leading reason for the hospitalization of children. For patients and their families, frequent visits to the emergency department are commonplace because many symptoms of a serious shunt malfunction – like sleepiness, headache, and vomiting – occur often in children. “Since our daughter was diagnosed with hydrocephalus, we’ve spent countless nights in the emergency room and endured multiple failed shunts. It’s a stressful lifelong challenge

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Figure 1: FlowSense

for kids and their families to live with this condition.” Recalls Pamela Crouthamel, the mother of a now-grown child who was diagnosed as an infant.

Despite widespread advancements in medical technologies and material durability, shunt failure rates due to mechanical breakdown, occlusion, and infection have remained high. Diagnosing these failures can be very challenging due to the unpredictability of occurrence, the non-specific nature of the symptoms, and the challenge of communicating with non-verbal children.

Current diagnostic methods also have inherent shortcomings. Brain imaging, for example, does not directly measure flow, but instead shows a surrogate measure of ventricle size while often exposing patients to harmful radiation. Alternatively, a shunt tap, in which a needle is inserted into the patient’s head to aspirate CSF, is invasive and can cause bleeding, infection, and fluid leakage. Importantly, none of these methods is highly predictive of shunt failure, with studies showing that x-ray assessment of shunt integrity, for example, is accurate in under 80% of cases. There is a clear and urgent need for improved capabilities in the assessment of shunt functionality. The traditional methods neurosurgeons typically rely on have huge drawbacks and do not directly give provide the flow information that they need most for diagnosis.

To address this unmet need, Rhaeos, Inc, is bringing technology developed by Prof. John Rogers at Northwestern University to the bedside with their first product, the FlowSense thermal flow monitor, a noninvasive, wireless, and FDA breakthrough designated medical device that monitors CSF flow beneath the skin surface in minutes without any capital equipment.

The device will initially launch in the hospital to provide a rapid bedside spot check of flow and will be a single use disposable device. Later, a reusable, rechargeable patch for home use will launch for longitudinal flow tracking. The battery-powered device simply sticks to the skin over a palpable shunt like an adhesive bandage. It delivers a small amount of heat to the skin that is imperceptible to the patient and measures the skin temperature at multiple spots underneath. When fluid is flowing in the shunt, the skin will be cooler upstream, or closer to the head, than downstream because heat dissipates in the direction of flow. When there’s no flow, the heat stays the source and there is no difference in the upstream and downstream temperatures. The FlowSense device transmits the temperature information wirelessly to a mobile app where an algorithm analyzes the data.

Rhaeos is currently conducting its pivotal study at 10 (adult and pediatric) hospitals in the US from coast to coast in support of FDA marketing authorization. Earlier studies have also been published in the Science Translational Medicine and Nature Digital Medicine journals, validating the company’s patented technology in assessing flow non-invasively. Additional studies are planned for 2023 focusing on clinical and economic based outcomes and future research initiatives include further development of the platform technology to assess other chronic conditions. Companies interested in clinical collaborations should email info@rhaeos.com.

Rhaeos’ work has been funded by private and institutional investors, the National Institute of Health (NIH), National Science Foundation (NSF), and several pediatric device consortiums such as the West Coast Consortium for Technology & Innovation (CTIP), National Capital Consortium for Pediatric Device Innovation (NCC-PDI) and the UCSF-Stanford Pediatric Device Consortium. Rhaeos is also part of the MedTech Innovator, KidsX Accelerator, Cedars-Sinai Accelerator, and gBETA MedTech portfolios.



Figure 2: FlowSense adhered on the surface of the skin ready to take flow measurements.

Innovations Education in Pediatric Urology: Reflections and Perspectives from Students and Faculty at an Academic Medical Center

Authors: Marie Luff,¹ Neha Iyer,² David Zarrin,¹ Stephanie Seidlits,³ Liang Gao,² Li Zhou,¹ Renea Sturm¹

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Urology is a technology-driven field with a strong track record of early adoption of novel medtech solutions. However, unique challenges to innovation exist in pediatric specialties such as pediatric urology due in part to regulatory burden, ethical considerations, and limited funding sources. These subspecialties are poised to benefit from early analysis of potential barriers to innovation by leveraging formal multi-disciplinary collaborations. This article describes the feasibility and experience of our newly developed formal innovations training across the engineering and medical schools. In this multi-disciplinary venture, pediatric urology was a test specialty selected for innovation student training, needs mapping, and prototype development and testing, with an added emphasis on the developing trainee skills of multidisciplinary teamwork and engineering design within each respective field. Put together, we propose that programs such as this one are a powerful method to engage students across disciplines early in their training and to define needs and novel solutions within subspecialty fields that may have fewer resources for innovation.

This year-long collaborative effort began as a summer innovations course developed for medical students at the David Geffen School of Medicine at UCLA in conjunction with the organization Sling Health¹, which incubates medical technology ideas of students. Eighteen medical students received training in the Biodesign process² and was tasked with performing a medical ethnographic analysis to identify unmet clinical needs in a specific clinical setting. This was achieved by directly observing and documenting current clinical practice, without interfering in the delivery of healthcare. Medical students conducted interviews across stakeholders, including the perspectives of health care staff, patients, and family members. Following this, identified clinical needs underwent a stepwise validation and prioritization process which included an early evaluation of the market potential, regulatory risk, and current and developing technology. Overall, the course was a success, with student confidence in key innovation skills increasing by an average of 190% (survey results).

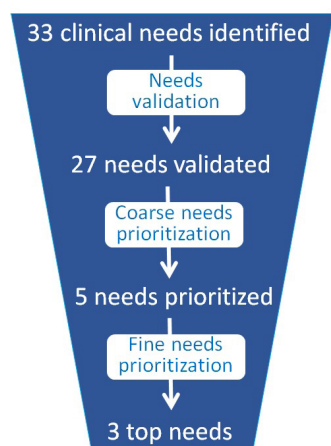


Figure 1: Needs analysis

One clinical focus area was pediatric urology in this summer program was pediatric urology. The medical student in this program was paired with a translational urologic surgeon-scientist mentor who had formal training in the innovations process³. Over the six-week observation period, 33 clinical needs were identified and codified. After further needs validation and prioritization, three top needs were determined (Figure 1). These three top needs were: 1) Parents and children need a faster treatment option for resolving nocturnal enuresis (NE) that also prevents incontinence during the treatment phase. 2) Physicians and parents need an accurate method to differentiate between undescended versus retractile testes at-home and in the outpatient setting to reduce unnecessary surgical referrals and procedures and 3) There is a need to reduce complications and readmissions associated with post-operative catheter obstruction after urologic procedures. Results from this project were subsequently presented and published⁴ by the medical student researcher and collaborative team (Figure 2).

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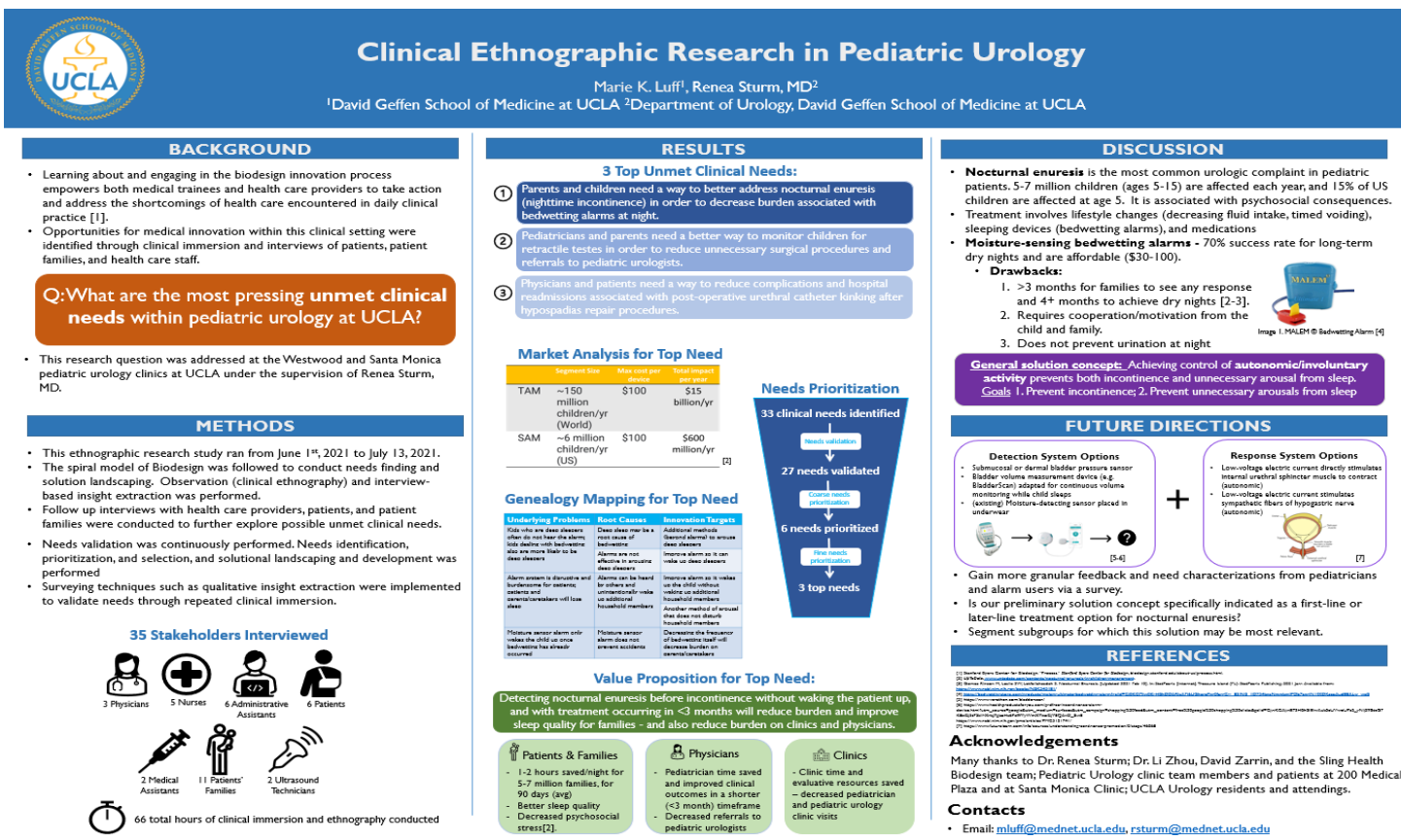
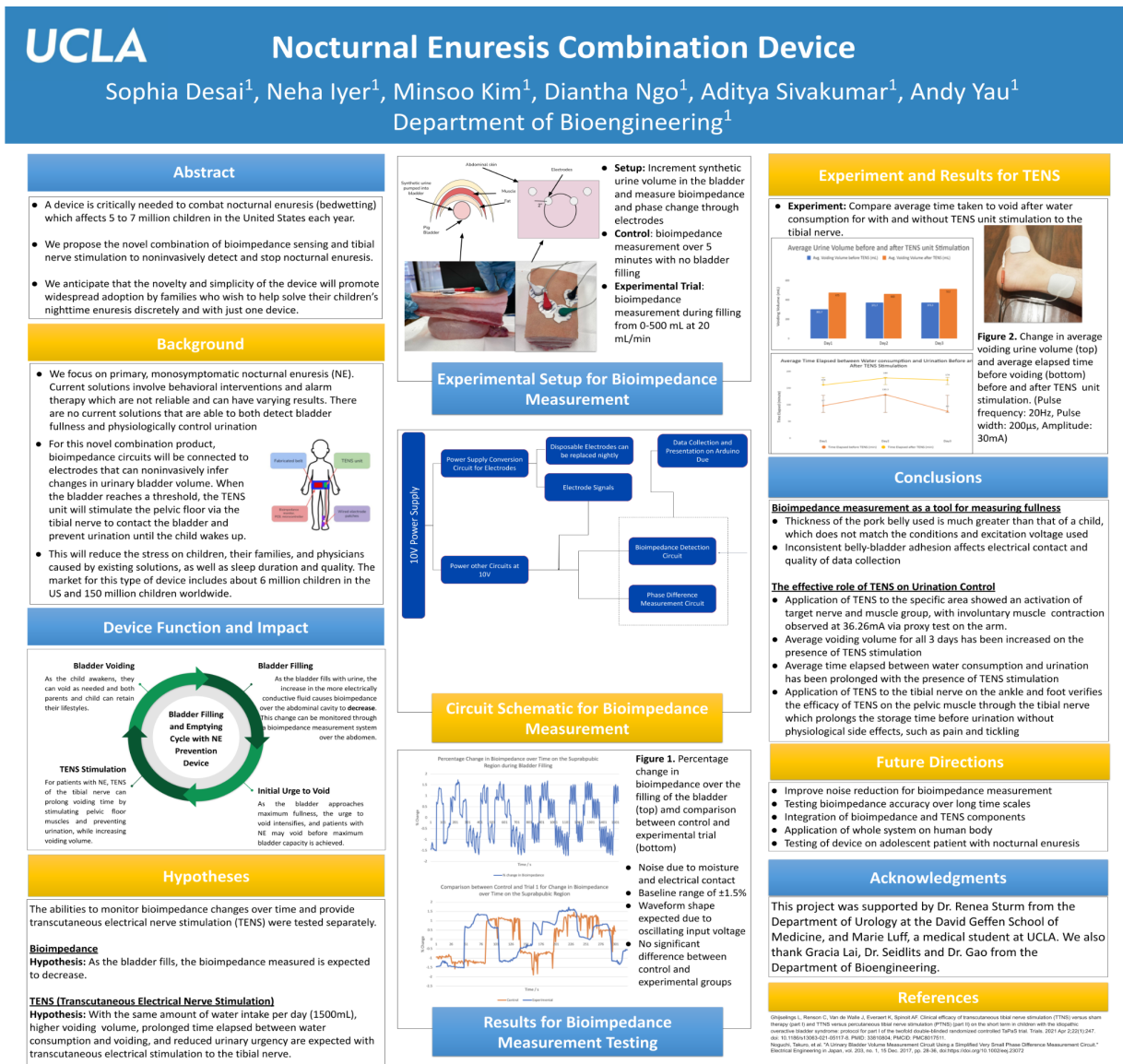


Figure 2. Medical School Biomedical Innovations Presentation

To pursue the top need identified, this work continued the subsequent academic year in collaboration with the UCLA Department of Bioengineering Capstone Design Course. The engineering student team consisted of six students with diverse interests ranging from medicine. Leveraging prior research, device design, and project management experiences, the team worked interdependently to determine clinical needs and necessary device features. The students met biweekly with a medical faculty and medical student, and weekly with a graduate student mentor for nine months. Over the two-quarter course, the students held over twenty team meetings and presented intermittent results to the bioengineering class on a weekly basis. Lectures provided by bioengineering faculty and biotech/entrepreneurial guests addressed topics such as planning and executing translational research.

Due to pandemic related restrictions, students worked remotely and in pairs to create each component of the proposed device during the fall, followed by lab-based testing of design components in the spring. The final prototype design included development of a belt-like combination device that could integrate bioimpedance sensing and TENS stimulation to treat pediatric primary NE. To test the prototype, a benchtop test using a porcine bladder and skin for the bioimpedance sensing component was designed and executed. Separately, TENS stimulation on the tibial nerve was evaluated by healthy test subjects to analyze effects on voided volume. Preliminary results indicated the potential for efficacy of a combination device and were presented as a poster by all team members (Figure 3) at the Bioengineering Capstone Symposium in spring 2022.

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How to Join ...

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There are NO DUES to join the SOATT

Send an e-mail to Jackie Burke at jburke@aap.org to request to be added to the Section.

Reflections:

Reflection 1: *My role on the engineering team was developing the volume-sensing unit. We used bioimpedance technology for this, and I worked on creating the benchtop test for our prototype. What was really cool about this project was that it uses relatively simple technology and carries the potential to alleviate significant lifestyle burdens. Not only did I get to think about how to build this device from a technical standpoint, but I also learned which features would be most important for children's ease-of-use and comfort. This project makes me excited for the future of medical technology and growing trends of patient-centricity in biodesign.* - UCLA Engineering student

Reflection 2: *Sling Health LA is an exciting new venture that leverages the strength of the L.A. medtech development ecosystem, including faculty with translational research experience, several of whom trained through programs such as the UCLA Biodesign fellowship in Innovation and/or have startup companies within the UCLA Biodesign and other L.A. accelerator and incubator programs. Faculty have the opportunity to benefit from the fresh perspective of medical students early in their training, experiencing the healthcare system for one of the first times during medical school. Medical students are empowered to approach the healthcare system as active participants in progress, rather than merely observers, and to learn early the inherent value of all stakeholders in the healthcare system. The partnership across the medical and engineering schools resulted in a powerful educational experience, maximizing the impact of the program not only by supporting the development of a working prototype, but more importantly by providing early education in effective multidisciplinary communication and teamwork that is required to move from a need into translational product development.* - DGSOM Faculty member

Reflection 3: *As a medical student participating in this process, I feel extremely grateful to have had the opportunity to work with such bright minds in engineering. Medicine remains a fairly insular field with few individuals looking outside of their area of expertise to brainstorm and collaborate with experts in other fields. Innovations work opens the door for these types of collaborations to occur, and offers a fresh perspective in solving problems that have been observed and overlooked in medicine.* - DGSOM Medical student

Moving forward, the team has completed further feasibility testing and analysis of the proposed market and looks forward to future collaborative ventures. The experience has bolstered the collaborations between the engineering and medical school innovations programs. We look forward to continuing to build upon this multi-disciplinary education based on participant feedback such that the next generation of researchers are empowered with the skills needed to effectively identify and address the range of needs that they will encounter in their respective careers.

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SOATT Update - August, 2022

By Amy Ohmer

abbyclark@icanresearch.org



The International Children's Advisory Network, Inc. (iCAN), is pleased to highlight the 2022 iCAN Summit presented by Jumo Health. Annually, through the expertise of our youth members, parents, community and sponsoring partnerships, iCAN provides an important focus on pediatric medicine, clinical research, medicine development, and medical device innovation. For 2022, the iCAN summit was held during July 11th - July 15th in Lyon, France under the hosting of the iCAN KIDS France Chapter led by Segolene Gaillard.



2022 iCAN SUMMIT

presented by



WITH SPECIAL
THANKS TO



At iCAN, our goal is to get kids where they need to be to have their voices heard. iCAN's amazing youth make a difference throughout all facets of pediatric healthcare and clinical research, through interactions with industry, by presenting original research at conferences, by innovating new solutions, by advocating for the pediatric patient voice in healthcare world-wide, and by telling their stories at conferences and to organizations like the FDA, NIH and NORD. This amazing opportunity is made possible by the support of donors like you as well as sponsoring partners. If you are interested in supporting iCAN, please consider this link - we will even send a special thank you gift of our brand-new iCAN Book for donations at \$25.00 or more USD. To donate, please visit <https://www.icanresearch.org/donate>.

The exciting week, led by Leanne West, President of iCAN, includes a jam-packed week-long agenda designed to immerse attendees of all ages into the world of healthcare and clinical research. Welcoming the nearly 189 attendees, including 80 young people between the ages of 10-18 years old, from four continents, Leanne's opening remarks inspired a week of learning and networking. As Leanne shared, at iCAN, the focus is on working together to help improve the quality of clinical care, research, and education through the expertise of our community. Along with Leanne, iCAN Board of Directors, Dr. Chester Koh (Secretary), and Jon Haygood (Treasurer) led the event with providing insight to the history (and future programming) of iCAN.



To further set the positive tone of day 1, the first speaker was a young person, Amelia Williams, who shared her personal story of living with a rare disease. To watch her presentation, visit <https://www.youtube.com/watch?v=ddl7fXCRZgI&feature=youtu.be>. Following Amelia, attendees

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began efforts on an innovation project around ‘Serious Games’ and the development of gamification designed to support medical treatment for in-patients in an effort to reduce patient anxiety, stress as well as, to increase learning about disease, medication, and treatment pathways.



Additionally, the iCAN Summit includes impactful workshops and learning sessions from community stakeholders. The sessions are favorites of youth members as they provide a two-way interaction of sharing experiences and expertise from both the pediatric patient population and the stakeholders that are helping to improve medicine, medical devices and clinical research. Special thank you to Jumo Health, Pfizer, Lilly, Labcorp, Pediatric Trials Network, Duke Clinical Research Institute, Georgia Tech, AAP SOATT, and Everylife for their support in making the week happen.



Further sprinkled throughout the week of the iCAN Summit, iCAN Youth Members participate within events like the iCAN Poster Session in which their local and international chapter projects are featured to help support idea exchange and innovation amongst the community. To see all of the posters submitted for 2022, please check out this link at <https://www.youtube.com/watch?v=Qk4sdF4BNgl>.

Both the iCAN Youth Council (YC) and the iCAN Young Adult Professionals (YAP) group take active leadership roles during the week. The iCAN YC is led by two young people: Mitali Vedula and Nadia Ansari. Both youth members have been a part of iCAN for several years and have moved into various leadership roles at their local chapters (KIDS CT and KIDS CHOC-RADY). While Mitali was unable to attend the summit, Nadia was there to support attendees and created an informative presentation to encourage young people to share

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their voices as well as a hands-on activity for young people to write and express their gratitude for participating at the summit.

Additionally, Rhiannon Perry led the YAP during the week. The YAP group is for young adults (ages 18-25) that want to remain connected to iCAN to continue to participate in leadership activities, mentoring, and also internships. To learn more about Rhiannon and to work with our iCAN Young Adult Professionals group, please visit this link at <https://www.icanresearch.org/ican-young-adult-professionals>.

iCAN also supports a parents and siblings chapter to help better understand voices that may not always be heard. Led by Deb Discenza and Jen Degl, this group held sessions as well as provided peer support to other attending parents during the week.

Additional highlights:

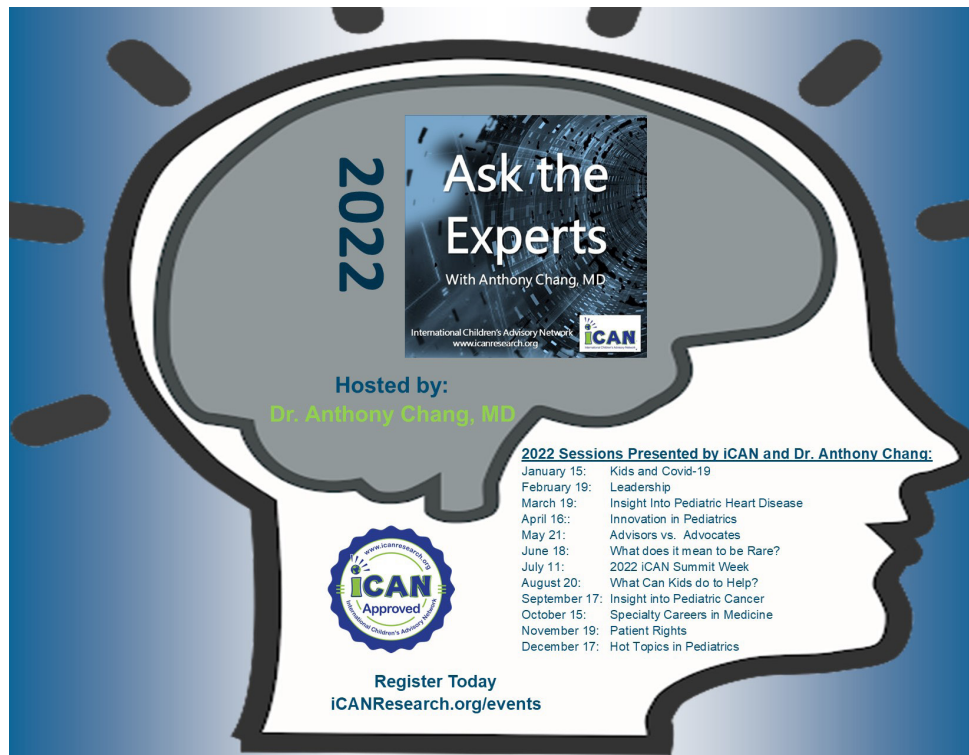
- Bringing together over 80 young people. *A special recognition to our KIDS Uganda Chapter, KIDS CHOC-Rady, and KIDS Moorefields Eye for their first summit appearances!*
- A week-long iCAN youth member innovation project designed around the development of Serious Games.
- Interactive and informative sessions hosted by Jumo Health, Pfizer, Labcorp, Lilly, Pediatric Trials Network, and Everylife.
- Learnings from Clinical Researchers, Doctors, Nurses, and other experts from throughout Europe.
- “Think Like A Doctor” session led by Dr. Sharon Smith, Chapter Leader, KIDS Connecticut and her team of medical students.
- Submissions of a total of 31 global Posters Abstracts from 28 iCAN Chapters, 2 individual youth members, and 1 sponsor partner.
- Special learning meetings co-led by iCAN Parents, iCAN Youth Council, iCAN Young Adult Professionals/YPAG Mentors, and iCAN Chapter Leaders.
- Visits to HCL Hospital and the University of Lyon throughout the week....and many cultural activities; including a monument scavenger hunt and a special Bastille Day celebration with dinner and dancing.
- Awards for iCAN Scholarship Winners, Duke Clinical Research Institute (DCRI) 2022 Anthology Submissions, and special thanks awarded to Segolene Gaillard, Chapter Leader, for her wonderful dedication to making the week a success for all attendees.
- If you would like to review the 2022 summit, please visit www.icanresearch.org/2022-summit.

The upcoming summit will be held from July 10th-July 14th, 2023 in Southern California. To learn more and to keep in touch with summit planning, visit <https://www.icanresearch.org/2023-summit>.

Even though the summit week is over, at iCAN, we want to help you with learnings from our youth members. To do this, we have a special monthly event called, “iCAN Ask the Experts” (ATE). This event focuses on youth member small group discussion on relevant

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topics within pediatric healthcare and research. After each session, iCAN provides a written summary of topics, along with a video recording of the session to ensure that information is shared to help improve patient experience. To participate in our ATE sessions, please email us info@icanresearch.org.



SAVE THE DATE:

- iCAN 'Ask the Experts' sessions take place on select Saturday mornings. For more information, please visit [HYPERLINK "http://www.icanresearch.org"](http://www.icanresearch.org)
- Join iCAN and the 2023 American Academy of Pediatrics National Conference and Exhibition in Washington DC. More details to come in the near future

A Message from the Membership Committee

Our Section continues to grow and now has over 1,000 members!

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:

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

Membership applications can be found at:

Members: <http://membership.aap.org/Application/AddSectionChapterCouncil>

Affiliates: <https://membership.aap.org/Application/SectionAffiliate>

If you have any questions about membership, please contact Chris Rizzo MD FAAP at crizzo624@gmail.com or Jackie Burke at jburke@aap.org.

Welcome New SOATT Members (March 2022 to October 2022)

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Hans Arora, MD, PhD
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Announcements from the AAP

Have You Visited SOATT's Collaboration Web Page?

<https://collaborate.aap.org/SOATT>

Only basic information about SOATT is on AAP.ORG

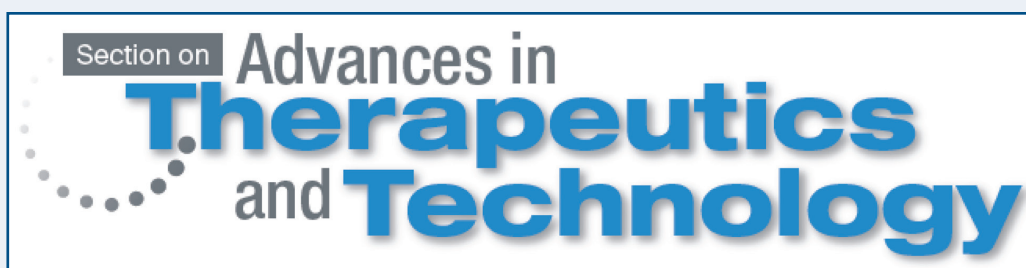
<https://www.aap.org/SOATT>

All of the members-only documents are on the collaboration page. Check it out!

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>



**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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at ckoh@bcm.edu

Byron Alex, MD, MPH, FAAP (Therapeutics Co-Editor)

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and

(Ryan) Brandon Hunter, MD, FAAP (Devices Co-Editor)

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