Section on Advances in Therapeutics and Technology Newsletter

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

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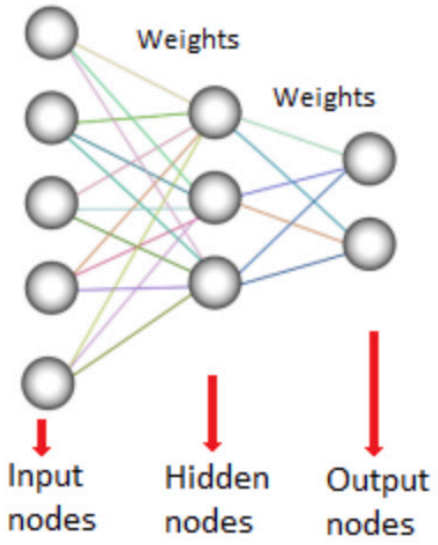
From the Editor's Desk: A Brief Primer on ChatGPT and Large Language Models

Hello all! My name is Brandon Hunter, and I'm very happy to serve as one of the editors for the AAP SOATT Newsletter. I wanted to take the opportunity to write briefly about Large Language Models (LLMs) which have been a passion of mine over the last few years. Most of us have heard about ChatGPT in the news, and whether you sit in the camp of wondering whether this is an overhyped text completion algorithm or the first sign of the arrival of our AI overlords, having a basic understanding of how these models work will be critical for clinicians and industry professionals alike in the coming years. There are a TON of articles exploring how LLMs may be applied in clinical decision support, patient and clinician education, and administration. Instead of reiterating those points here, I wanted to just briefly talk about how the models are trained and function to help empower clinicians and industry professionals interested in engaging with their early application.

Unpacking the Definition

Large Language Models (LLMs) are advanced AI systems designed to process, understand, and generate human-like language based on vast amounts of text data. They are artificial neural networks made up of **nodes** which are the basic units of the network that can process information. These **nodes** are connected by **parameters** which represent the weights and biases of the model and allow it to process information in complex ways.

So "Large" in the term Large Language Model usually refers to the number of parameters (weights/biases) present – there were 175 billion parameters in GPT-3 (the old model powering ChatGPT), and though we can't say for sure, likely as many as a trillion in the newer version powered by GPT-4. "Large" can also refer to the amount of text data used to train the models, also on the order of billions of webpages.



(Figure source: https://www.saedsayad.com/artificial_neural_network.htm)

How are LLMs Trained?

We say that LLMs are trained on billions of webpages of data, but what does this really mean? One common example of a training strategy is known as Masked Language Modeling, which is a type of self-supervised learning. Basically, the model takes a sentence of text from the internet and randomly masks some words (or more specifically, "tokens," which are small pieces of meaningful text) within the sentence. The objective of the model is to predict these missing words/tokens based on the context provided by the unmasked words. After making a prediction, the model compares its guess to the actual text observed on the internet to learn and adjust its contextual associations. Over time, the model can predict that certain words will appear at certain frequencies based on exposure to billions of webpages.

Continued on Page 2

With this in mind, we can see how the models are prone to bias. The model, for example, would likely associate the north pole with words like cold, snow, freezing, etc., because they tend to be written about together on the internet. Problems can arise if similar language associations arise based on text observed about groups of people and can lead to potential bias within the system. Not discussed here, but even after these associations are made, Reinforcement Learning from Human Feedback (RLHF) is a critical (and often cryptic) part of determining the LLM's ultimate behavior and very much dependent on company-specific human input and guidance.

Continued on Page 3

IN OUR ISSUE

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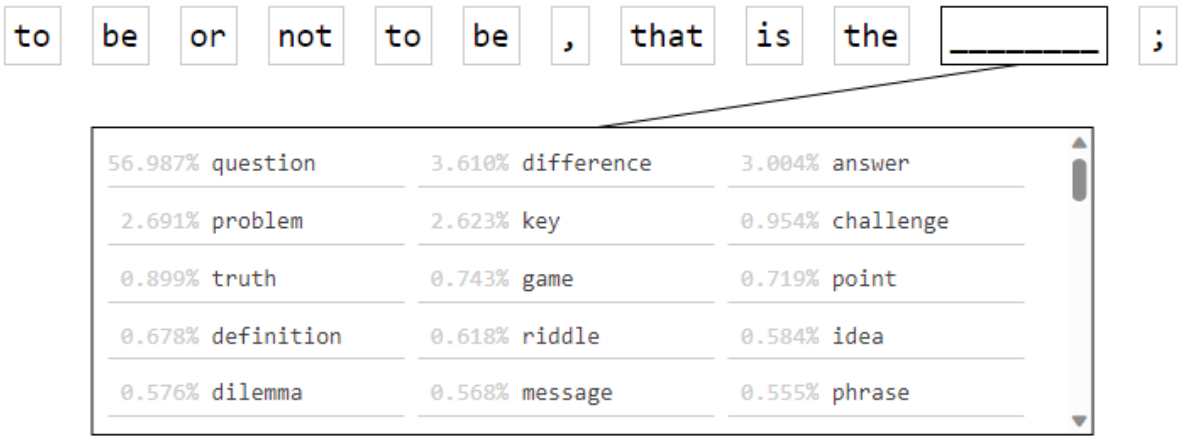


In this example, the model knows that *usually* the next word in this sentence is 'question,' *but* other words do still appear, though less frequently (Merve, N. (2023). Fill-in-the-blank. Hugging Face Spaces. https://huggingface.co/spaces/merve/fill-in-the-blank).

How do LLMs Work?

Stephen Wolfram has a phenomenal article that anyone interested in the subject should read (see figure citation), so much what follows is based on his impactful writing. At the end of the day, LLMs like ChatGPT/GPT-4 generate natural-sounding text by selecting words (tokens) that form a "reasonable continuation" of whatever text has been provided input text – this process is not so different from the completion training discussed above. The model's parameters, adjustable numerical values that define its architecture, capture relationships and weigh dependencies between words (tokens), enabling the model to predict the likelihood of a what the next string of text should be based on its prior training.

{The best thing about AI is its ability to,
The best thing about AI is its ability to learn,
The best thing about AI is its ability to learn from,
The best thing about AI is its ability to learn from experience,
The best thing about AI is its ability to learn from experience.,
The best thing about AI is its ability to learn from experience. It,
The best thing about AI is its ability to learn from experience. It's,
The best thing about AI is its ability to learn from experience. It's not}

learn	4.5%
predict	3.5%
make	3.2%
understand	3.1%
do	2.9%

Wolfram, Stephen. (2023, February 14). What Is ChatGPT Doing … and Why Does It Work? Stephen Wolfram Writings. https://writings.stephenwolfram.com/2023/02/what-is-chatgpt-doing-and-why-does-it-work/&#8203

So, in the example above, ChatGPT knows that when it has seen the text "The best thing about AI is its ability to…", the next most common text it has observed is "learn," so it puts in that text. It now has a new string of text and repeats this process over again. It is remarkable to note that whether ChatGPT is answering a question or writing a book, it is simply repeating this process over and over again – asking itself "given the text here so far, what is a reasonable continuation at this point?"

This explains the basic idea, but what about creativity? Well, by adjusting a feature called the "temperature," a LLM will randomly

Continued on Page 4

choose a text continuation that is *not* the most common choice (in the example above, it might choose "predict" or "make" rather than "learn"). By doing this, the model can generate creative, interesting, and human-like responses. I personally have to pinch myself to remind me that this is how it works – there is almost nothing in my direct experience of reading the well-organized and formatted responses of ChatGPT that indicate this is what's going on!

I hope this was helpful! Understanding the basics of how the models are trained and function is critical to understanding their current strengths, limitations, and risks. I do believe these models will have an incredible impact with how we deliver care to children in the coming years and am excited to see how the AAP SOATT can help lead in this space! On a selfish note, if anyone is interested in researching or collaborating on work implementing these models, please get in touch!

Thanks so much for reading,
R. Brandon Hunter, MD, FAAP
rxhunter@texaschildrens.org

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/

SWPDC - AAP SOATT Pediatric Device Prizes for Fall 2023

Chester J. Koh, MD, MBA, FACS, FAAP and **R. Brandon Hunter, MD, FAAP**
Texas Children's Hospital, Baylor College of Medicine,
and the Southwest 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 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 2023 will be announced at the SOATT session at the 2023 AAP NCE in Washington DC. We look forward to seeing you there!

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 and Jhalak Mehta and R. Brandon Hunter) 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 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.

2023 AAP NCE - SOATT Program Highlights

The annual SoATT program will be held during *AAP Experience* on Monday, October 23, 2023 in the Marriott Marquis (Salon 14) from 9:00 – 11:00 am. The program '*OK Boomer, OK Zoomer: Leveraging Technology to Enhance Patient and Family Engagement'* will feature a cross-generational panel of experts in technology development. The session is intended to foster an appreciation of the myriad of available technologies that can enhance clinician and clinician researcher's engagement with patients and families. The session will also provide pearls on which tech tools are situationally appropriate in practice versus in research, provide a roadmap on how to vet new technologies, as well as how to stay astride of the pace real-time tech evolution.

The Section Meeting will also be used to bestow the eighth annual SoATT Achievement Award for Pediatric Innovation. The 2023

Continued on Page 6

honoree is Dr. Anthony Chang (Chief Intelligence and Innovation Officer and the Medical Director of the Heart Failure Program, Children's Hospital of Orange County). The section meeting will conclude with the awarding of certificates to the top three research papers in the area of pediatric innovation.

We look forward to seeing you in Washington, DC.

H4001 Section on Advances in Therapeutics and Technology

OK Boomer, OK Zoomer: Leveraging Technology to Enhance Patient and Family Engagement

Monday, October 23, 2023 Marriott Marquis Washington DC Salon 14 EASTERN TIME ZONE

09:00AM	**Welcome and Introduction** Christopher Rizzo, MD, FAAP (SOATT Section Chair)
09:05 AM	**Moderated Panel Discussion** **OK Boomer, OK Zoomer: Leveraging Technology to Enhance Patient and Family Engagement** Moderators: Amy Molten, MD, FAAP (Executive Committee Member, SOATT) Panelists: Sharief Taraman, MD, DABPN, DABPM, FAAP (Chief Executive Officer, Cognoa; Former Division Chief, Associate Professor, Pediatric Neurology, Children's Hospital Orange County) Shireen Atabaki, MD, MPH, FAAP (Professor of Pediatrics & Emergency Medicine, The George Washington University School of Medicine; Associate Medical Director, Telemedicine, Children's National Hospital) Sneha Dave – Family Representative, Founder and Executive Director, Generation Patient
10:30 AM	**Section Award & Brief Awardee Remarks** Moderator: Christopher Rizzo, MD, FAAP (SOATT Section Chair) Award Recipient: Anthony Chang, MD
10:45 AM	**Section Awards for Top Three Research Paper Presentations** Moderator: Chris Rizzo, MD, FAAP (SOATT Section Chair)
11:00 AM	**Adjourn**

See SOATT Posters in the Exhibit Hall Immediately following the program!

2023 SOATT Accepted Abstracts

2023 SOATT ABSTRACT PROGRAM		Presenting Author Information		
Presentation Title	Submission Type	First Name	Last Name	Credentials
Long-Term Safety and Sustained Efficacy of Dupilumab Treatment in Children With Moderate-to-Severe Asthma: LIBERTY ASTHMA EXCURSION	Original Research	Nicholas	Jellots	n/a
Dupilumab reduces rescue systemic corticosteroid use in children with uncontrolled moderate-to-severe asthma while improving lung function, regardless of prior exacerbation history	Original Research	Nicholas	Jellots	n/a
Earliest known craniopagus parasiticus magnetic resonance imaging with associated 3D model	Case Report	Devashish	Joshi	MD
Novel Automated Orchidometer for Accurate Point-of-Care Testicular Volume Measurements in Pediatric Patients	Original Research	Chester	Koh	MD
Treatment of refractory norovirus enteritis in a pediatric hematopoietic stem cell transplant patient	Case Report	Ekra	Rai	MD
Online for Omnipod: Examining Attitudes and Information Related to Type 1 Diabetes Omnipod 5 Device on TikTok	Original Research	Kara	Sangiuolo	BA
Intraoperative and Short-term Postoperative Complication Rates for Robotic-Assisted Placement of Over 1,500 Pedicle Screws in Pediatric Posterior Spinal Fusion	Original Research	Jenna	Wisch	BS
Dupilumab Treatment of Children with Moderate-to-Severe Atopic Dermatitis Increases Bone Alkaline Phosphatase, a Marker of Bone Mineralization	Original Research	Henry	Yu	n/a
Efficacy and Safety of Evinacumab in Pediatric Patients with Homozygous Familial Hypercholesterolemia	Original Research	Shazia	Ali	MD
Glucagon Fills and Costs Among Children and Adolescents with Type 1 Diabetes, 2011-2021	Original Research	Tyler	Benning	MD, MS
4-Phenylbutyrate for children with STXBP1 and SLC6A1 mutations - a pilot clinical trial	Original Research	Jennifer	Cross	MD
Pediatric Industry and NIH-funded Clinical Trials vs Pediatric Burden of Disease in the United States from 2015-2020	Original Research	Ansh	Goyal	n/a
Trabecular Bone Score Reference Values for Mexican Children and Adolescents	Original Research	Miguel Angel	Guagnelli	MD, MSc

Continued on Page 8

Efficacy and safety of linaclotide in treating functional constipation in pediatric patients aged 6–17 years: a phase 3, pivotal, randomized, placebo-controlled trial	Original Research	Susanna	Huh	MD, MPH
Durable improvement in glycated hemoglobin in youth-onset type 2 diabetes: a post hoc analysis of the DINAMO trial of empagliflozin and linagliptin versus placebo	Original Research	Lori	Laffel	MD
Factors Influencing the Decision to Express Human Milk: A U.S. Based Mixed Method Study	Original Research	Kimberly	Rosenbaum	MSN, RNC-OB, C-EFM, IBCLC
Effect of Omalizumab on Asthma Outcomes in Pediatric Patients with Asthma and Food Allergy	Original Research	Dawn	Sibanda	MD, PharmD, MPH
Digital Streaming for Cochlear Implant Users: Navigating Barriers to Improve Music Enjoyment	Original Research	Shreya	Srivastava	MBA
Therapeutic cancer vaccines in the management of neuroblastoma: A Systematic Review	Original Research	Angelina	Uzor	n/a
ECMO Cannula to Dialysis Catheter Exchange Using a Modified Seldinger Technique	Case Report	Healy	Vise	BS

Highlighted abstracts win top abstract certificates.

KidsX: Pushing Boundaries in Pediatric Digital Healthcare – Deepa Shah

As part of CHLA's Office of Transformation, the CHLA Innovation Studio launched KidsX in 2020 – a global ecosystem of pediatric innovators that facilitates collaboration between multisector partners, including children's hospitals, providers, payors, investors, entrepreneurs, and corporate partners, to solve the most pressing problems in pediatric care delivery. KidsX delivers accelerators and innovation programs to support digital health companies achieve product/business model validation in the pediatric market. KidsX is anchored by a consortium more than 30 of the leading children's hospitals in the US and around the world.

Startups selected to be part of KidsX programs receive (1) Mentorship and learning curated to their business and growth needs, (2) Networking opportunities with investors, payors, hospital leaders and other subject matter experts (3) Pitch practice and feedback with potential partners and customers (4) Product market fit feedback and validation (5) KidsX support in navigating through hospital operational and administrative hurdles (6) Digital health adoption support.

KidsX has graduated six classes of digital health companies since 2021 through the flagship KidsX accelerator programs and two corporate partnership accelerator programs, with Amazon Web Services and Press Ganey. In total, 57 startups have graduated the accelerators. Over 60 pilots are in process and/or have been completed between the graduated startups and the KidsX Hospital Consortium. In addition to executing accelerator programs, KidsX executes innovation challenges focused on public health issues like obesity, mental and behavioral health, food shortages/insecurities and vaccinations. Previous innovation challenge partners include Elevance Health, Microsoft, City of Glendale, and Los Angeles County Department of Health.

KidsX also launched a partnership with Redesign Health, called KidsX Build. If there isn't an existing startup in the market that addresses

Continued on Page 9

the needs of a KidsX member hospital, the program is designed to identify, build, and scale new innovative healthcare companies that address the needs of pediatrics patients, clinicians, and service providers. Through KidsX Build, Redesign Health and KidsX member hospitals regularly convene to review areas of opportunity to build new healthcare companies together and incorporate perspectives from member hospitals as the pediatric healthcare landscape continues to evolve. KidsX members also gain early access and insight into pediatrics-related ventures being created at Redesign Health, with the opportunity to shape these solutions as they develop.
KidsX is focused on expanding its mission and ability to positively pediatric healthcare outcomes through innovation and technologies. If you'd like to be a part of the KidsX network, please reach out to kidsx.health@gmail.com

Pediatric Device Spotlight – SMöLTAP Infant Spinal Tap Positioning Device

SMöLTAP™

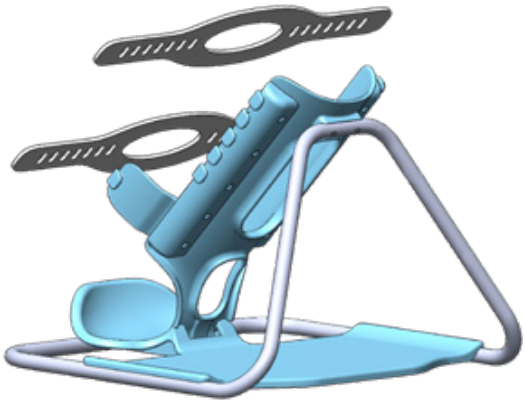
Advancements in medical technology continue to transform the way healthcare professionals diagnose and treat various conditions, especially in pediatric care. Among the groundbreaking innovations is the SMöLTAP Infant Spinal Tap Positioning device. This cutting-edge device has revolutionized the process of performing spinal taps on infants by ensuring accuracy, safety, and minimizing discomfort for the little patients.

Designed by doctors, the SMöLTAP device addresses the unique challenges associated with performing spinal taps on infants. Traditionally, this procedure has been challenging due to the positioning of the infant's spine and reliance on an experienced 'holder.' However, with the introduction of the SMöLTAP device, healthcare providers now have a reliable tool that simplifies the process, ultimately enhancing patient outcomes.

The SMöLTAP device helps align the infant's spine with shoulders and hips as well as flex the infants back while seated, without a human holder, creating a stable, consistent and accessible space between the vertebrae. Additionally, a face opening allows for easy breathing and application of a pacifier and sucrose. Combined, SMöLTAP reduces the risk of complications and unnecessary discomfort. By providing healthcare professionals with a consistent repeatable solution, the SMöLTAP device ensures that the procedure is performed quickly, with the utmost precision and care.

Furthermore, the SMöLTAP device incorporates mechanisms to minimize the potential risks associated with spinal taps. It includes features such as an infant being gently held in an upright position, biocompatible straps and shoulder guards to ensure that the procedure is carried out with heightened safety. This not only enhances the safety of the infant but also provides healthcare providers greater comfort as the need for a "holder" is no longer necessary and assistants can focus on patient comfort and care.

In conclusion, the SMöLTAP Infant Spinal Tap Positioning Device has emerged as a game-changer in pediatric care. By combining consistent positioning, stability and infant focused features, this device has significantly improved the accuracy, safety, and overall experience of performing spinal taps on infants. As medical technology continues to advance, innovations like the SMöLTAP device pave the way for more effective and compassionate care for our youngest patients, setting a new standard in pediatric healthcare. For more information, please visit the SMöLTAP website: www.smoltap.com.



Baylor College of Medicine Texas Children's Hospital is hosting the second Pediatric Paracorporeal and Extracorporeal therapies Summit (PPETS) - Ayse Akcan Arikan, MD

Pediatric paracorporeal and extracorporeal therapies (PPET) are increasingly applied to support children with multiple organ failure (MOF). These highly complex, resource intensive technologies lie at the interface of innovation and the highest complexity clinical care. It is not uncommon that in patients with MOF, multiple treatment modalities are used simultaneously. Lack of clinical guidelines or consensus to guide PPET use may result in a lack of standardization of practice, compounded by limited dialogue between experts and institutions regarding PPET use, in particular in the application of multiple PPET modalities. Children are further disenfranchised due to the lack of medical devices optimized for the varied size and physiological differences in pediatric practice. Identifying a critical need for collaborative initiatives aimed at standardization of practice, quality improvement, research and innovation as they relate to the applications of PPET, Baylor College of Medicine Department of Pediatrics Division of Critical Care Medicine was awarded a R13 grant by the *Eunice Kennedy Shriver National Institute of Child Health and Human Development* to host a unique summit.

The first Pediatric Paracorporeal and Extracorporeal Therapies Summit (PPETS) in October 2022 brought together, for the first time, pediatric and adult experts from across the globe in the fields of extracorporeal membrane oxygenation, ventricular assist device, renal replacement therapy, extracorporeal liver support, and apheresis. The first Summit provided an initial framework to optimize the care of these patients and improve their outcomes by defining the current status of PPET, including the role of hybrid and tandem therapies; standardizing current approaches; identifying key knowledge gaps that need to be addressed to facilitate optimal patient care, and set a collaborative research and quality agenda to improve our understanding of PPET. This exciting and much needed framework provided the initial steps of collaboration to optimize the care of these patients and improve their outcomes.

Preconference working groups, led by experts selected by the diverse organizing committee around the *core domains* worked in a series of virtual meetings to maximize global participation in the months prior to the Summit to generate a comprehensive agenda. The Summit itself included state of-the-art presentations from the experts to define the current status, underlining the importance of cross-pollination of multiple therapies and approaches.

Six domains were identified by the international organizing committee to be priority areas for focus:

- Patient and family experiences and outcomes
- Ethics
- Standardization of terminology and quality metrics
- Pharmacokinetics
- Circuit and organ interactions and cross-talk
- Innovation

Dr. Kate Brown, Great Ormond Street, London, UK was the international chair of the meeting, while Theresa Mottes and Dr. Corey Chartan served as the national and local chairs, respectively. The 2022 meeting was on a virtual platform due to challenges created by the COVID-19 pandemic and obstacles to travel with fluctuating disease activity across the globe. With over 400 registrants, the meeting was well attended.

We are highlighting the work of three domains herein: Ethics, quality and standardization, and pharmacokinetics.

Ethics: As the available devices and indications for mechanical circulatory or device support expand, more and more ethical challenges are arising. From equitable access, evolving standards of care, candidacy, to length of therapy and resource allocation, several ethics topics were addressed in PPETS 2022 by a panel of pediatric ethics experts from around the world. Moving forward, this domain continues to work on ethical challenges associated with device use in pediatric patients. Targets this year include device use in low and middle-income areas around the world, development of a standard ethics framework that can be implemented for any device in any location, and development of guiding principles to try to encourage just and equitable device access from industry.

Quality and Standardization: Under the PPETS "Quality and Standardization" domain, the PPETS faculty sought to use modified Delphi consensus to create standardization recommendations within PPETS. The approach included systematic review of literature

Continued on Page 11

and a national survey focusing on current nomenclature being used. There were four key questions: 1. Is the current nomenclature being followed? 2. Is this true in the pediatric space? 3. How are circuit integrations talked about? 4. How can nomenclature promote standardization? The primary goal of the survey development was to identify currently utilized nomenclature for circuits incorporated as PPET in pediatric critical care.

The survey was designed as longitudinal and utilized an electronic platform with the target population of international healthcare professionals with expertise in critical care, ECLS, and/or nephrology. Although the response rate was modest at 20%, we had over 500 respondents. The content included topics related to ECMO and CRRT circuit structure and function, nomenclature and management of anticoagulation and circuit changes, integrated circuits, and open-ended responses.

Heterogeneity existed in responses for ECMO nomenclature for structure and less so in management with anticoagulation and circuit changes. In CRRT, there was more consistency in nomenclature in relation to circuit structure and modality. Majority were able to identify tandem CRRT and slow continuous ultrafiltration (SCUF) but integrated dialysis within the ECLS circuit was not equally recognized. Key barriers that included lack of standardized training, platforms, and environments were identified. Suggestions for the future include the importance of clear diagrams and manuals with a unified platform.

Pharmacokinetics: Evidence has suggested that an important driver of PPETS related mortality may be altered drug disposition due to a combination of underlying illness, patient-circuit interactions, and drug-circuit interactions. ECMO and/or CRRT patients routinely receive more than 20 medications, and data supporting optimal dosing for most of these do not exist. The PPETS gathered an international group of experts in the fields of ECMO, CRRT, and other PPET modalities to discuss the current state of these therapies, disseminate innovative support strategies, share clinical experiences, and foster future collaborations. The experts concluded that specific medications must be prioritized for in-depth study to improve drug use in PPET and patient outcomes. A list of high priority drugs was compiled based on frequency of use, potential for adverse outcomes if dosed inappropriately, and lack of existing PK data to stimulate and guide future PK research. Additionally, consensus was built on reconsidering study designs, through pooling of resources through multi-center studies and the use of innovative PK modeling techniques. The expert group emphasized that the integration of validated PK models into clinical practice must be streamlined to deliver optimal medication use at the bedside. PPETS 23 will continue this work by highlighting innovative techniques for PK research and raising awareness around the proposed priority medications and key methodological considerations to contribute to future robust research efforts.

The second meeting is planned for October 16-18, 2023 as a hybrid platform, combining an in-person meeting with a virtual option to optimize access for especially resource limited settings. Main goals of the meeting are to:

- Describe the current state of extracorporeal therapies in resource limited setting and low middle income countries
- Compare existing liver support systems and examine implementation gaps
- Apply translational research concepts to novel clinical trial designs to understand development as a biologic variable
- Identify gaps in knowledge for current use of therapeutic apheresis in the intensive care units to inform a research agenda
- Build consensus on core elements for quality science in extracorporeal therapies by catalyzing standardization of terminology
- Examine nutritional practices in adults and children on extracorporeal therapies to identify knowledge gaps
- Implement best practice for pharmacokinetic supported therapeutic drug monitoring in extracorporeal therapies

Attendance is free for trainees and recorded content will be available to registrants for 90 days after the conference.

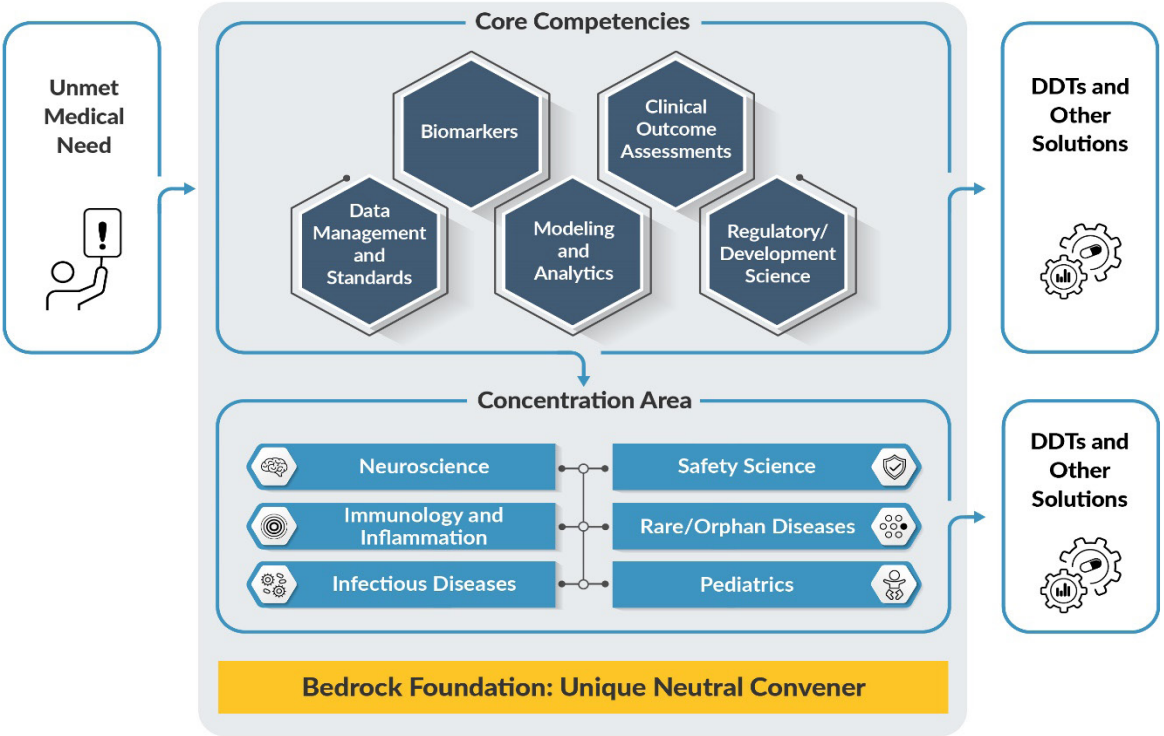
The in-person attendees will also have the option to participating in a simulation experience focusing on combined circuits.
Conference website: https://whova.com/web/Lww4UXV-m9HL6eifKYpvA%40ygdaKLBOBsmGh9PV5gHVQ%3D/

The Critical Path Institute: leading public-private collaborations that accelerate drug development across the lifespan

Gina Calarco Smith, MPH, RN; **Krista Casazza, PhD, RD, CSSD**; **Joseph Hedrick, PhD**; **Kanwaljit Singh, MD**
Pediatrics Program, Critical Path Institute
Email: gsmith@c-path.org

At the Critical Path Institute (C-Path), the aim is to accelerate the drug development process, making it more efficient for everyone. Through forward looking programs and diverse stakeholder discussions we support work in the pre-competitive space to innovate and solve some of the most complex issues drug developers face. We are unique because we provide a neutral space where pharmaceutical companies, regulatory agencies, scientists, clinicians, and advocates can share data and information, which we then integrate to generate actionable solutions that remove bottlenecks. This way, drugs can be developed and approved faster, which improves the health of people worldwide. See a snapshot of C-Path's core competencies and areas of concentration for unmet drug development needs in Figure 1.

Figure 1



One of C-Path's fastest growing programs is the Pediatric Program, which encompasses four public-private partnerships: the International Neonatal Consortium (INC), Type 1 Diabetes Consortium (T1DC), and two new consortia launching in the Fall of 2023. The Critical Path for Alpha-1 antitrypsin deficiency (CPA-1) and Critical Path for Lysosomal Disorders (CPLD) will each bring together global industry, academic researchers, patient groups, and regulators to build consensus and collaborate towards drug development solutions for unmet needs specific to these populations and diseases. As with the existing consortia, the newly launching consortia will serve as a conduit for critically assessing drug development tools with the anticipation of having these tools moved forward through regulatory channels, supported by aggregated data sharing. The data platforms and interrogation or modeling constructs, and regulatory submission pathways and process are supported through C-Path providing a unique neutral entity to bring competitors together and develop solutions that are publicly available and free for use. C-Path is a mission driven organization focused on impacting patients' lives positively. An overview of each of the established and launching consortia within the growing pediatrics program are detailed below.

Continued on Page 13

International Neonatal Consortium (launched 2015)

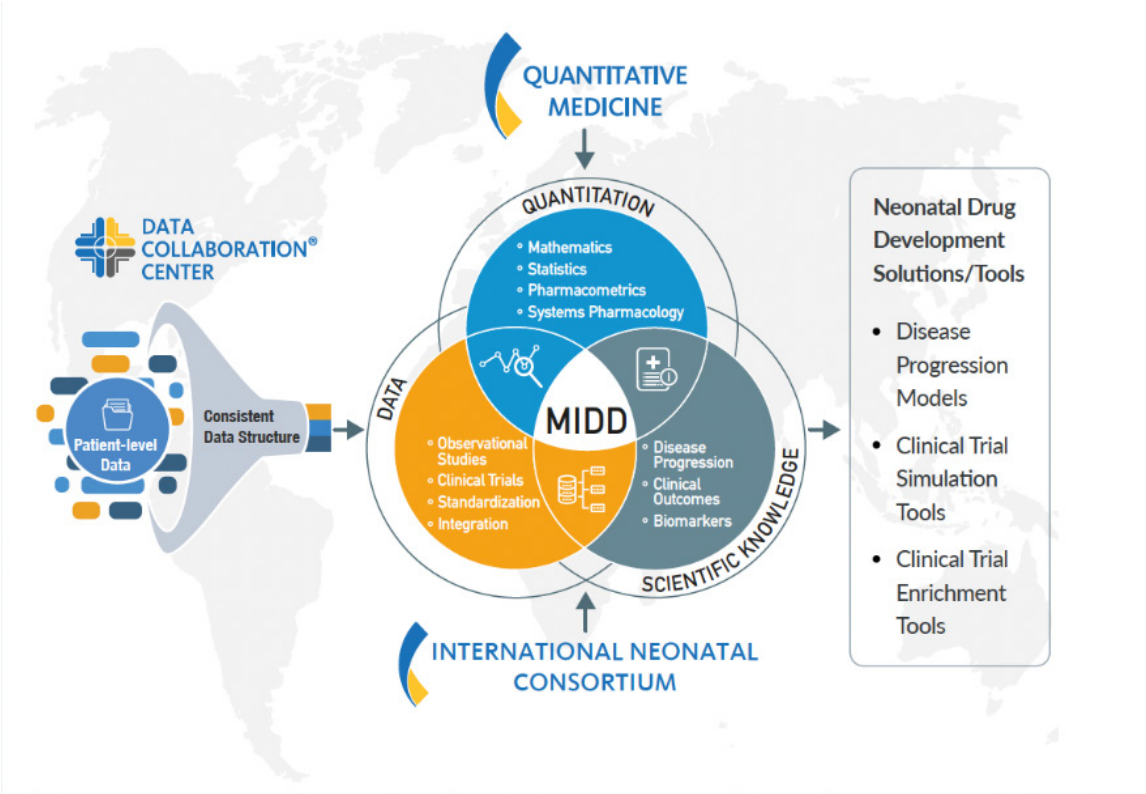
The International Neonatal Consortium (INC) is a founding consortium of C-Path's pediatric program, addressing the needs of both preterm and term neonates. It comprises professionals from industry, academia, clinical settings, families, and regulatory bodies, all of whom collaborate to promote innovation and enhance drug development for neonates.

A significant initiative by the INC is the Real-World Data Analytics Platform (RW-DAP), which contains over 300,000 data entries from neonatal electronic health records, registries, and clinical trials. This platform is designed to develop disease progression models and offer neonatal lab reference ranges based on age, gender, ethnicity, and other patient parameters.

The consortium has working groups that cover areas such as neonatal nurse education, bronchopulmonary dysplasia, brain injuries, seizures, neonatal abstinence syndrome, hemodynamic adaptation, among other challenges in neonatal intensive care units.

Over its 8-year span, the consortium has rolled out tools like the Neonatal Adverse Event Severity Scale (NAESS), which is acknowledged by the National Cancer Institute / National Institutes of Health (NCI/NIH) and used by regulatory entities for neonatal clinical trial safety reporting[1]. Additionally, INC's proposal for standardized neonatal blood pressure measurements aims to provide consistency in measurements, potentially benefiting both clinical trials and routine care[2]. The consortium has also provided recommendations for conditions like retinopathy of prematurity[3], necrotizing enterocolitis[4], and neurodevelopmental follow-ups[5]. A detailed overview of INC's process for drug development tool solutions can be found in figure 2.

Figure 2



Type 1 Diabetes Consortium (launched 2017)

Type 1 Diabetes is an autoimmune disease that can begin at any time in life, proceeds silently for years (or decades in some cases), and results in the loss of insulin production and lifelong diabetes. The burden of living with this disease is high and complications from the disease can be severe. For over 100 years the only treatment has been to administer insulin, typically by injection or pump to replace

Continued on Page 14

what has been lost, a situation that only recently has begun to change. The T1DC was established in 2017 with the goal to significantly advance the drug development landscape for T1D prevention and treatment. The consortium achieves this by fostering collaborative relationships within the broader T1D community and sharing data, knowledge, and resources to promote the development and regulatory endorsement of novel drug development tools. A significant achievement has been the European Medicines Agency qualification, in 2022, of islet autoantibodies as enrichment biomarkers for T1D prevention clinical trials[6] and an FDA opinion on the same subject published in the medical journal Diabetalogia[7]. Today the T1DC is working with a wide range of investigators, patient advocacy groups, and industry participants to build sophisticated models of disease progression that will enable faster development of novel therapies to prevent and treat T1D.

Critical Path for Alpha-1 antitrypsin deficiency (to launch Fall 2023)

Alpha-1 antitrypsin deficiency (AATD) is a rare genetic disease that predominantly presents as chronic obstructive pulmonary disease in the fourth decade of life and has a sub-population of infants presenting with liver disease. To date, drug development efforts have been challenged by a lack of endpoints effectively measuring change over a reasonable time or requiring an unrealistic number of patients for this rare disease. C-Path's goal through pre-consortium work has been to establish a sustainable public-private partnership which will facilitate the advancement of medical product development in AATD to improve the health of patients living with AATD, across the age continuum. The consortium will kick off with a focus towards non-invasive means of detecting and evaluating progression of lung and liver disease through evaluating computed tomography lung density and liver elastography datasets. The alignment of diverse stakeholders to identify challenges, prioritize solutions, and develop new tools will encourage new product development to meet the most pressing needs of people living with AATD.

Critical Path for Lysosomal Diseases (CPLD, to launch Fall 2023)

Lysosomal storage diseases (LDs) are a group of inherited metabolic disorders caused by the deficiency of enzymes necessary for the breakdown of certain molecules in the lysosome. When lysosomal enzymes responsible for the breakdown and recycling of various molecules in the cell, including lipids, proteins, and carbohydrates are deficient, they accumulate in the lysosome, leading to cellular dysfunction and tissue damage. There are over 70 diverse types of LD, each caused by a specific enzyme's deficiency. Accordingly, the pathophysiology of LDs is complex and varies depending on the specific disease. LDs affect several organs and systems in the body, with over 75% displaying direct central nervous system (CNS) involvement. The severity of the disease, the inclusion across organ systems, and the specific symptoms depend on the type of LD and the degree of enzyme deficiency. There is no cure for LD and limited treatments based on specific LD. Treatment can involve enzyme replacement therapy (ERT), substrate reduction therapy (SRT), gene therapy (GT), or in some instances solely supportive care to manage symptoms. Early diagnosis and treatment are important in preventing or minimizing irreversible damage to affected tissues and organs.

Both CPA-1 and CPLD pre-consortia work has been funded through grants from the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER). Work began in 2022 to conduct landscape and gap analysis of potential common biomarkers or other measures that could be used to accelerate drug development. With the valuable insight of diverse, global stakeholders from industry, academia, patient groups, and the FDA, consensus has been developed to identify and address unmet needs and potential drug development tools to spur on novel therapies for patients living with these rare diseases.

CPA-1 and CPLD consortia will officially launch in October 2023, with ongoing consensus building and review of datasets from clinical trials, longitudinal research, and registries to support the full consortia three-year research plans targeted towards biomarker identification and context of use. Upon launch, the consortia will move towards clinical trial and longitudinal research (anonymized) data aggregation and building consortia specific data platforms to support the identification of regulatory acceptable biomarkers. In addition, these two consortia will devote a portion of their inaugural year evaluating the landscape and unmet drug development needs related to regenerative medicine (cell and gene-based, etc. therapies) in pediatrics and through the life of these patients. If you would like to learn more about CPA-1 or CPLD consortia contact Colleen Jacobsen, project manager, or meet the team and stakeholders at the 2023 C-Path Scientific Breakthrough Summit.

C-Path will be hosting a Scientific Breakthrough Summit focused on the pediatric program consortia from **October 26-27, 2023, in Arlington, VA**. This is a free event offering further insights into the work C-Path does, networking opportunities, and discussion panels with regulators. The agenda is forward looking, exploring vulnerable population and rare disease drug development in the face of paradigm shifting regenerative and cell/gene-based therapies. This is a free event that follows the American Academy of Pediatrics

Continued on Page 15

National Conference & Exhibition (Oct 20-24) and is sure to generate deeper conversations and innovative ideas. Further information regarding the agenda and registration details can be found at the below website.

Home - Scientific Breakthrough Summit 2023 (cvent.com)

Citations

1. Development of a Neonatal Adverse Event Severity Scale. *Archives of Disease in Childhood* 2019;104:1167-1173. Scale available on NIH website. evs.nci.nih.gov/ftp1/Pediatric_Terminologies/INC/
2. Method of Blood Pressure Measurement is Critical in Neonates and Infants: A Systematic Review and Analysis. *J Pediatr*. 2020 Jun; 221: 23-31.
3. Development of a Retinopathy of Prematurity Activity Scale and Clinical Outcome Measures for Use in Clinical Trials. *JAMA Ophthalmol*. 2019 Mar 1;137(3):305-311.
4. Necrotizing Enterocololitis: Using Regulatory Science and Drug Development to Improve Outcomes. *J Pediatr*. 2019 Sep;212:208-215.e1.
5. Assessment of Long-Term Neurodevelopmental Outcome Following Trials of Medicinal Products in Newborn Infants. *Pediatr Res*. 2019 Nov;86(5);567-572.
6. Leveraging Real-World Data for EMA Qualification of a Model-Based Biomarker Tool to Optimize Type-1 Diabetes Prevention Studies. *Clinical Pharmacology & Therapeutics*. 2022 May;111(5): 1133-1141.
7. Utility of islet autoantibodies as enrichment biomarkers in type 1 diabetes clinical studies: a viewpoint from the FDA. *Diabetologia* 66: 603-604, 2023.

How to Join ...
It's easy! 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.

Empowering Transformations: From a Nursing Journey to Ask the Experts – Chronicles from the Heart of iCAN

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iCAN, or the International Children's Advisory Network, is committed to providing numerous opportunities for the pediatric community to come together and hear from the most crucial stakeholders in healthcare: the patients. Our organization is dedicated to empowering all pediatric patients worldwide by facilitating their active participation in innovation and research in medicine. Whether you are a patient, family member, healthcare professional, or supporter of the cause, we welcome you to visit our website at www.iCAN.health to learn more. 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.

Celebrating Remarkable Progress: Empowering iCAN Uganda Chapter Member's Pathway to Nursing and Medical Advancement

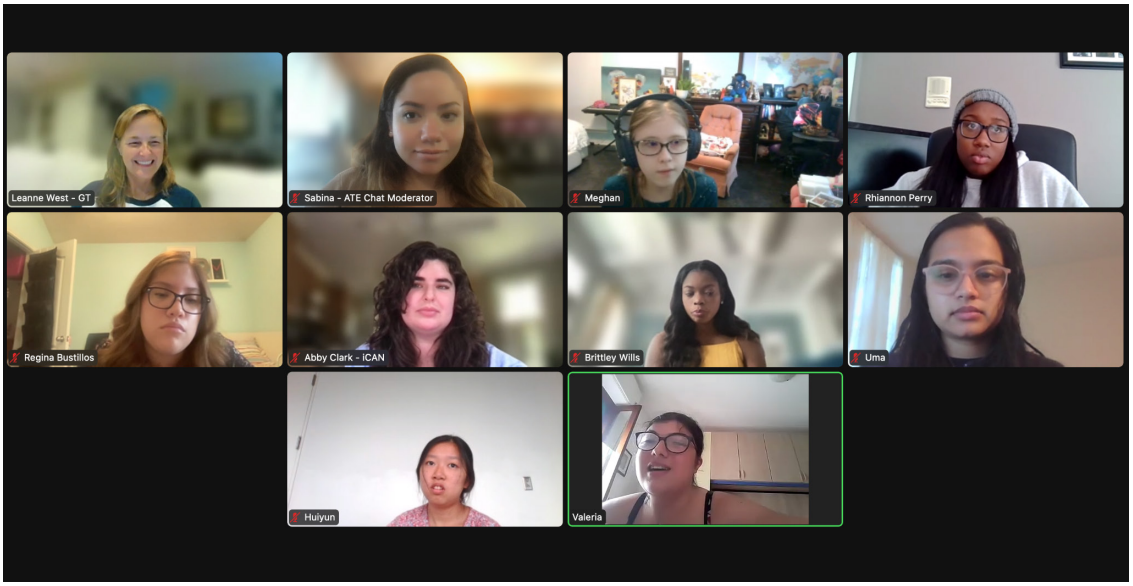
We are thrilled to share a heartening success story that exemplifies the transformative influence of iCAN's initiatives. One of our esteemed members from the iCAN Uganda chapter is charting a promising trajectory towards a career in nursing, poised to make substantial contributions within the medical domain thanks to the instrumental role iCAN has played in her journey. This inspiring narrative stands as a testament to the profound impact of iCAN's endeavors and the tangible outcomes they foster.

The fervent dedication and relentless efforts of this remarkable individual are indeed a testament to the nurturing environment and empowerment that iCAN provides. Her pursuit of a nursing career in Poland underscores the profound ripple effect that grassroots initiatives like iCAN can have on shaping lives and driving positive change.
As we witness the unfolding of her journey, we are reminded of iCAN's core mission: to provide a platform that not only educates and informs but also empowers individuals to transcend boundaries and realize their potential. This accomplishment fills us with immense pride and reaffirms our commitment to fostering avenues of growth, education, and empowerment within our diverse and global iCAN community.

We eagerly anticipate the continued progress and success of our dedicated iCAN Uganda member as she embarks on this transformative path within the medical realm. Her journey exemplifies the impact that passionate individuals, supported by organizations like iCAN, can have on shaping the landscape of healthcare and beyond.

Continued on Page 17

Navigating Medical Challenges: Insights from Experts and Their Transformative Journeys on "Ask the Experts"

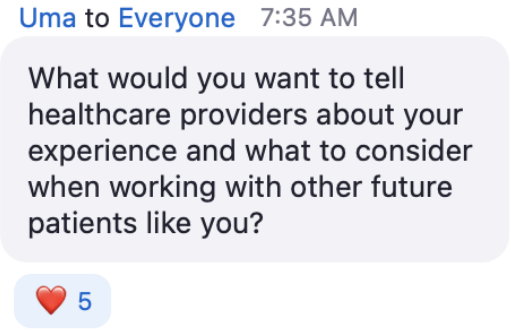


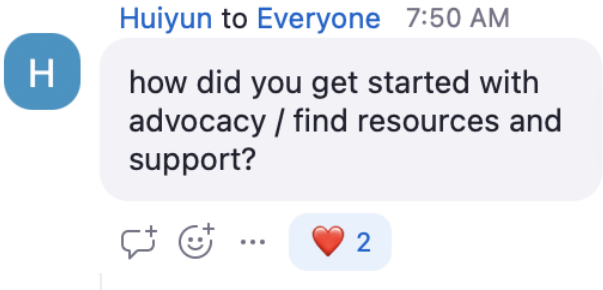
On Saturday, August 19th, an engaging and thought-provoking Ask the Expert session took place, centered around the compelling theme of "Transforming Adversity into Strength." This event featured a distinguished panel of experts: Meghan, Rhiannon, Regina, and Valeria, all of whom possess an unparalleled level of expertise as authorities on their own medical conditions. The crux of their discussions revolved around introspective inquiries, delving into their unique diagnostic journeys and the profound implications these journeys have had on their lives.

A prevailing topic that emerged was the transformative influence of confronting medical challenges. The panelists delved into how their encounters with adversity had fundamentally shifted their perspectives on life and its multifaceted hurdles. Particularly captivating was the exploration of positive aspects and silver linings that have emerged amidst the complex landscape of medical adversity. These individuals generously shared instances where they had gleaned valuable life lessons from their medical experiences—lessons that proved instrumental in surmounting challenges extending far beyond the domain of healthcare.

This event was a symphony of inspiring personal narratives, conveying how these medical journeys have not only shaped the lives of the panelists but have ignited an unwavering desire to provide support and inspiration to others navigating similar hardships. Each panelist elaborated on their unique approaches to motivate, assist, and provide solace to individuals facing comparable struggles.

The impact of this session was palpable, serving as a resounding testament to its profound influence on attendees. The engaged and inquisitive audience seized the opportunity to pose thought-provoking questions, fostering a dynamic discourse that further enriched the collective experience.





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Our iCAN community is excited to extend an invitation to you for the ongoing journey of enlightenment and empowerment through our highly anticipated Ask the Experts (ATE) series. This monthly series showcases luminaries from diverse fields, including healthcare, technology, and innovation. We wholeheartedly encourage you to secure your participation for the forthcoming ATE session in September by registering on our website. By engaging in these sessions, you open the door to engaging discussions and the accumulation of invaluable insights.

We warmly welcome all interested parties to join us in these enlightening sessions. To stay informed about upcoming ATE topics and session dates, please follow our Instagram account, @icanresearch.

At the core of iCAN's mission lies an unwavering dedication to providing a platform for experts to share their wisdom and experience. If you possess expertise in pediatric healthcare—whether in the realms of innovation, medicine, or technology—we enthusiastically invite you to contribute as a speaker for our ATE sessions. For additional information, kindly contact us at abbyclark@icanresearch.org. This presents a rare opportunity to deeply immerse yourself in the knowledge and insights of top-tier healthcare experts. We urge you to promptly reserve your spot for the upcoming ATE session, as we eagerly anticipate your active engagement and participation. Your journey toward enlightenment and empowerment commences here.

Excitement Builds for the iCAN 2024 Summit in Bari, Italy- Sponsorships Needed!

We are thrilled to announce that our much-anticipated 2024 summit will be hosted in the beautiful city of Bari, Italy! The excitement among our kids is palpable as they eagerly look forward to this incredible event. However, we need your help to make it a truly unforgettable experience for all!

Our annual summit provides invaluable opportunities for our young members, similar to the ones previously offered by Empath Labs and Pfizer. It serves as a transformative platform for fostering innovation, compassion, and collaboration in pediatric healthcare.

If you believe in the power of education and inspiration, we invite you to be a part of this life-changing event. There are two ways you can contribute:

1. Sponsor the 2024 Summit: By becoming a sponsor, you will play a crucial role in supporting the logistics and organization of the summit. Your generous contribution will enable us to create an impactful and seamless experience for all participants. To sponsor the event, please reach out to sabinaschmidtgoldstein@icanresearch.org.

2. Sponsor a Child to Attend the Summit: Your sponsorship can directly impact the life of a child, providing them with a once-in-a-lifetime opportunity to attend the summit in Bari. Your support will cover their travel, accommodation, and participation fees, allowing them to immerse themselves in a world of learning, inspiration, and empowerment. To sponsor a child, please visit our donation page at https://www.icanresearch.org/donate.

Together, we can shape a brighter future for pediatric healthcare by nurturing the potential of our young members. Your contribution, no matter how big or small, will make a significant difference in paving the way for innovative advancements in the field.

Thank you for considering this opportunity to support the next generation of healthcare leaders. We are deeply grateful for your generosity and dedication to our cause. Let's come together in Bari, Italy, and create an unforgettable summit experience that will inspire and empower young minds for years to come!

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 (October 2022 to August 2023)

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Continued on Page 20

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Narendrasinh Parmar, MD, FAAP
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Ryann Sherman, PA

Continued on Page 22

Welcome New SOATT Members (October 2022 to August 2023) *Continued from Page 23*

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Allison Weisnicht, MD
Meredith Garst, DO
Brahmananda Koduri, MD, FAAP
Thomas Robitaille

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

Section on Advances in Therapeutics and Technology

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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