Reflections from the Chair

“Update on COVID-19”

Christopher Rizzo, MD, FAAP
Chairperson, AAP SOATT
Sanofi Pasteur
Email: crizzo624@gmail.com

More than 15 months after a COVID-19 vaccine was available for adults in the US, there remains none available for children under five years of age. There is no doubt it is challenging but I cannot help wondering if it would have taken this long if the disease were more severe in these young children than in adults? Would pediatricians have had to wait so long for something to protect their patients?

Necessity, as they say, is the mother of invention. Technological leaps sometimes occur all at once. Messenger RNA and viral vector vaccines, along with extended half-life monoclonal antibodies represent advances in prevention of infectious diseases that were slowly making their way through clinical development but were viewed as niche players compared to conventional vaccines. They work differently than typical vaccines. Rather than administering an antigen which causes the desired immune response, mRNA and viral vector vaccines instruct cells to make the antigen. Compared to conventional monoclonal antibodies which typically require monthly dosing to maintain serum levels, so-called next generation long-acting monoclonal antibodies, engineered to have an extended half-life, can provide protection for at least 5-6 months with a single dose, positioning them similar to seasonal prevention such as influenza vaccines.

The pandemic and the investment that came with it, propelled these new technologies forward. And while there were no shortcuts taken on determining safety and efficacy, the public in general, and specific groups in particular, are more deliberate in their acceptance. Some may say more “hesitant” which has a negative connotation. I prefer “deliberate” which implies weighing the benefits and risks which I believe most people do. But that implies that consumers have access to accurate (correct), reliable (won’t change on a whim), credible (authority), and trusted (cares about them) information and can separate it from the rest of the information swirl.

Pediatricians know they are the best source of information for their families. And while not every parent is going to follow their pediatrician’s advice, most will. At least they know where the pediatrician stands on an issue. There are few positions in life that have so much sway or influence on people.

A study of pediatric clinical trials recently published online in Pediatrics by Brewster et al (doi: 10.1542/peds.2021-052557) discovered that among pediatric clinical trials registered on ClinicalTrials.gov from 2007 to 2020, the leading reason trials were stopped early was due to recruitment failure. Enrolling children (and certain other segments of the population) in clinical trials requires more effort. But who better to make that effort and support the family by answering all of their questions than their trusted pediatrician? Federal legislation resulting in the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act argues that children should be protected through research, not protected from research. Shouldn’t that be a message every pediatrician can get behind?

Now I am not blaming the lack of a COVID-19 vaccine for children under five on pediatricians being unable to recruit

Continued on Page 2
children into clinical trials. But having more pediatricians involved in clinical trials or connected with a center conducting clinical trials and being the first to approach families about enrolling in a trial could go a long way toward increasing pediatric participation in trials. One of the resources that our Section has developed is a parent brochure “Should my Child Join a Clinical Trial?”

Our Section encourages pediatricians to educate their families about the importance of research and of participation in clinical trials. As a Section, we are working to increase educational activities for pediatricians to do just that. Our section is focused on collaboration among pediatricians working in practice, research, policy, government, and industry. Collaboration breeds innovation and children benefit from the advances in therapeutics and technology. Sometimes these happen gradually and sometimes these happen in leaps. We need to be ready for the leaps. We are planning new ways to mentor and network with members seeking opportunities to collaborate. Look for the opportunity to be listed in our new member directory and look for our SOATT H Program and Reception at the NCE in Anaheim. See you there!

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Be Informed! Get Involved!

Join the Section on Advances in Therapeutics and Technology Listserv® Today!
If you are interested in joining the Listserv, email Jackie Burke at jburke@aap.org
From the Editor's Desk:

“Welcome to our New Co-Editors for Pediatric Therapeutics and Pediatric Devices”

Chester J. Koh, MD, FACS, FAAP  
Newsletter Editor, Leadership Team, AAP SOATT  
Texas Children's Hospital / Baylor College of Medicine  
Email: cko@bcm.edu

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

We hope that all are well and enjoying the Spring weather

To meet the needs of our growing Section with over 1,000 members, we have added two newsletters co-editors who will focus on two primary areas of focus for our section: Pediatric Therapeutics and Pediatric Devices. Please welcome them at our next meeting!

Byron Alex, MD, MPH, FAAP (btalex@gmail.com) is our new co-Editor for Pediatric Therapeutics and is the medical director at Vertex Pharmaceuticals, Inc (Providence, RI). He supports the Cystic Fibrosis Therapeutic Area for Global Medical Affairs in North America, where his responsibilities include leading product launches, supporting external engagements for field Medical Science Liaison teams, and working with cross-functional partners to advance corporate objectives. He received his undergraduate BA degree from Wesleyan University, his MD degree from Weill Cornell Medical College, and his MPH degree from Columbia University, as well as completed his residency in pediatrics at New York Presbyterian Medical Center.

R. Brandon Hunter, MD (rxhunter@texaschildrens.org) is our new co-Editor for Pediatric Devices and is a pediatric critical care physician and Assistant Professor of Pediatrics at Texas Children’s Hospital and Baylor College of Medicine (Houston, TX). He received his undergraduate BA degree and MD degree from University of Virginia, as well as completed his residency in pediatrics at Boston Children’s Hospital and Harvard Medical School and his pediatric critical care fellowship at Children's Hospital of Philadelphia and the University of Pennsylvania.

We look forward to seeing everyone at the NCE in Anaheim, CA in the fall (October 7 – 11, 2022) that includes the SOATT session. Safe travels for all of your adventures this spring, summer, and fall!

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. It 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/

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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

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

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Fall 2021 SWPDC and AAP Section on Advances in Therapeutics and Technology (SOATT) Pediatric Device Prize

Chester J. Koh, MD, FACS, FAAP FAAP and Kara Toman, MPH
Texas Children's Hospital, Baylor College of Medicine,
and the Southwest National Pediatric Device Innovation Consortium (SWPDC.org)
Email: ckoh@bcm.edu

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

Continued on Page 5
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 winner of the SWPDC and AAP SOATT Pediatric Device Prize for Fall 2021 is:

**Butterfly BVM / Compact Medical Solutions** (Dr. Jonathan Merrell – Indianapolis, IN)

Butterfly BVM is the first manual ventilator designed to allow delivery of specific tidal volumes to infants and small children, preventing lung damage and hyperinflation that can occur with current models. ([compactmedicalsolutions.com](http://compactmedicalsolutions.com))

We congratulate Dr. Merrell and Compact Medical Solutions as the Fall 2021 awardee! The next award cycle will take place in Fall 2022, and we encourage all pediatric device innovators in the AAP SOATT to apply.

We also wish to thank our SWPDC staff (Christine Luk at Fannin Innovation Studio in Houston, Texas and 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 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.

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**Pediatric Device Spotlight**

**OtoNexus Medical Technologies**

*Caitlin Cameron*

CEO, OtoNexus Medical Technologies  
Email: caitlinc@otonexus.com

The evaluation of Otitis Media (OM) has not changed significantly in 100 years. A change is long overdue. OtoNexus Medical Technologies has developed a breakthrough technology that instantly and accurately assesses middle ear effusion characteristics and gives physicians the data they need to accurately determine need for antibiotics. The device is designed to fit perfectly into their current workflow and provides results within two seconds.

OM is among the most common ailments in pediatrics, but its diagnosis is not straightforward. It is the #1 indicator for antibiotic prescriptions in children and the #1 cause for children's surgery. Over $5B is spent annually in the U.S. on treatments related to OM. Acute OM is widespread in children, affecting approximately 80% of children aged one and five years. At present, acute OM is primarily diagnosed clinically by observing the tympanic membrane appearance by otoscopic examination, combined with the patient's history and presenting signs and symptoms. This method has an average error rate of 50% for detecting the presence/absence of effusion. Further, the type of effusion behind the
tympanic membrane is essential for accurate differentiation between viral and bacterial infections, which drives clinical decision-making as to whether antibiotics are appropriate and indicated. Current otoscopic examinations are inadequate to differentiate the type of infection even when they successfully identify the effusion's presence.

In March 2013, the American Academy of Pediatrics (AAP) issued new guidelines for managing OM, urging primary caregivers to limit antibiotic use to those cases with unequivocal indications. These guidelines are intended to support the public health goal of containing acquired resistance in bacteria through reduced antibiotic prescribing and to allow the native immunity of the middle ear to resolve the infection. However, the multiple diagnostic uncertainties within current clinical practice result in significant over-prescribing of antibiotics and poor adherence to OM antibiotic prescribing guidelines. In addition, under-diagnosis can lead to eardrum perforation or even permanent hearing loss at the other end of the spectrum.

Unfortunately, today's physicians do not have the tools to provide accurate quantitative data for OM. They are in a frustrating and challenging position and may prescribe antibiotics “just to be sure” or address parental pressure to prescribe. Physicians may also suggest watchful waiting, but this can be inconvenient for working parents for whom an episode of their child's middle ear infection means no daycare and missing several days of work.

After caring for children for over 40 years, OtoNexus Founder and Chief Medical Officer George Gates, MD, was determined to find a better way to diagnose OM and treat these children. He was frustrated with the lack of accurate tools for analyzing OM and the resulting over-prescription of antibiotics. Fortunately, he met OtoNexus Chief Science Officer Mark Moehring, Ph.D., the inventor of transcranial Doppler ultrasound. Together, they thought ultrasound technology was a potential solution, given it is a highly accurate, well-known, and safe technology.

They had to overcome a significant technical challenge to make this a reality: applying ultrasound technology without using ultrasound gel. This had never been achieved before, but it is critical to success in the case of middle ear assessment. You can imagine that it is entirely impractical to fill a child's ear with ultrasound gel and then remove it when the examination is complete.

As a result of the vision of Drs. Gates and Moehring, OtoNexus developed a unique, patented, miniaturized ultrasound transducer less than 1 sq. mm that can fit into the tip of a disposable speculum. The proprietary speculum is attached to an advanced otoscope with an integrated camera to visually assess and capture images of the eardrum, while the ultrasound technology identifies both the presence and characteristics of the effusion behind the tympanic membrane.

The device resembles a handheld otoscope in shape and usage, to fit seamlessly into the current ear exam routine. It provides actionable quantitative data that is not available today with any other technology or tool, within two seconds. With this information, clinicians will be able to accurately identify when antibacterial therapy is appropriate and when it is not. The data can be shared immediately with parents and patients in the exam room to create alignment regarding the treatment plan and the use of antibiotics.

The Southwest Pediatric Device Consortium (SWPDC) has been a tremendous partner for OtoNexus. They immediately understood the profound, positive impact of the device on the effective evaluation and treatment of OM and promoting good antimicrobial stewardship practices for pediatric patients. Not only did the SWPDC support OtoNexus with a grant to advance product development, but they also provided critical introductions to clinical researchers at Baylor College of Medicine. As a result, the OtoNexus team is working on a study with the prestigious otolaryngology department at Texas Children's Hospital. The prospective study compares the ultrasound findings with the surgeon's rating and lab analysis of middle ear effusion found at surgical myringotomy. The study findings will be used to finalize the software algorithm on the device for the middle ear effusion analysis. Working in the clinical environment is also an opportunity for the OtoNexus team to obtain valuable physician feedback to ensure the device is easy to use as well as shortens total examination time.

Physician feedback for the device is very positive. They greatly desire a tool that will provide accurate quantitative information to determine when antibiotics are appropriate, allow them to better comply with the AAP guidelines, and improve patient care by minimizing repeat visits and improving the quality of specialist referrals.

Continued on Page 7
OtoNexus will market the device to pediatric clinics, emergency departments, and urgent care clinics. The company’s goal is to provide a simple, accurate non-invasive tool in assessing OM early in the care path to reduce the use of unnecessary antibiotics by 50%. This technology innovation can potentially change the clinical assessment of OM. It will be the first real improvement in evaluating middle ear infections in the past 100 years.

For more information, contact Caitlin Cameron, CEO, OtoNexus Medical Technologies, at caitlin@otonexus.com.

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**The Great Investigator Gap in Sponsored Pediatric Clinical Trials**

Gina Calarco MPH, BSN, CCRC  
Sr Director Strategy & Planning  
LabCorp, Rare Diseases, Advanced Therapies, and Pediatrics Team  
Email: gina.calarco@labcorp.com

The landscape of industry (pharmaceutical or device) sponsored clinical trials in pediatric populations has made enormous gains since regulatory mandates first were introduced in the 1990’s. However, the ability to recruit patients into these trials has faced significant challenges thus dampening the progress. A major issue for recruitment is related to the finite number of pediatric research sites interested and capable of conducting these regulatory mandated trials.

In the US the FDA pediatric regulations have been outlined within the Pediatric Research Equity Act (PREA). This legislation has the aim to progress knowledge and data impacting pediatric clinical care through incentives and mandates for conducting pediatric clinical trials following approval of an IND in an adult population. Since this legislation was first introduced in the 1990’s, mandates have expanded into pediatric oncology (FDA Reauthorization Act of 2017 (FDARA) and device work (2007 Pediatric Medical Device Safety and Improvement Act). This has led to more pediatric clinical trials and data which offer insights and care decision support resulting in a positive impact to pediatric medicine and patients.

Various researchers have published on the challenges related to recruitment for pediatric clinical trial work. Per a 2018 publication from Hwang et al, nearly 2/3 of pediatric IND trials between 2007 and 2014 were discontinued or had not reached enrollment targets within 6 years of starting. This poses a significant hardship for sponsors, investigators, and most importantly the patients and families participating or looking to the research community and IND/device trials to develop new care options.

Publications and reported metrics have noted several reasons for not meeting enrollment goals. While it is true that pediatric, indication specific populations are limited and even considered rare by some; the 2020 US census showed approximately 22% of the population was less than 18 years of age. This offers perspective to set our expectations and grow our potential to improve how we conduct and meet the recruitment for PREA mandated trials. We will always experience a more limited and shifting pool of pediatric patients but there is the opportunity to expand access to clinical trial work to reach more of the pediatric population.

Having worked in the pediatric clinical trial space for over 15 years, at both a site and now from a contract research organization (CRO) perspective, there is a supply and demand issue at play that is greatly impacting the ability of these trials to enroll and produce meaningful data and expanded choices for pediatric medicine. While there has been needed and successful growth of pediatric investigational new drug trials (demand), there has not been the same growth in developing new investigators and sites with access to a more diverse and broader pediatric population (supply).

The large academic pediatric centers are arguably the best centers for complex indications or advanced therapies where multiple sub-specialists and diagnostic capabilities are required. However, problems arise due to a funnel effect limiting the number of trials an investigator can support both from a recruitment/patient pool perspective but also a resource perspective. Factors affecting the resource funnel include clinical care and academic responsibilities and access to trial coordinators. Many of these centers are also involved with government and consortium work which may be prioritized.
creating further barriers to successful recruitment and completion of industry sponsored trials. When these known centers are unable to recruit or reject a study due to resourcing, competition, or lack of patient population the trial often has to extend timelines (at best) or abandon the trial (worst case), as there are only a finite number of experienced sites and investigators with no good mechanism in place to develop new sites and investigators. This leaves valuable research questions unanswered and data unpublished, the exact opposite intention of the regulations.

Within the industry sponsored clinical trial space, CROs and sponsor companies often seek participation from the same investigators and sites, predominantly large academic pediatric centers in urban areas. As noted, these centers house diverse sub-specialty pediatricians, diagnostic capabilities, research experience, and access to known pediatric patient populations. While these centers have conducted high quality clinical trial work for decades, and will remain a key entity for research projects, they cannot fill the overwhelming need for pediatric patient enrollment in the expanding clinical trial space. This begs the question for how to increase access to and improve the diversity of pediatric patients recruited into clinical trials while also helping to fix the supply and demand issue currently being experienced.

The pandemic has further exacerbated issues in conducting pediatric clinical trials as we have seen impacts on human resources at the known sites across all research roles, from loss/aging/retirement of pediatrician researchers, nurse study coordinators, administrative or support staff, and the institutional review boards. Even prior to the pandemic, one article noted the impending problem of aging medical researchers and a lack of younger investigators. This leaves us with an even greater risk of delaying or stalling out important work to further advance pediatric clinical care. Those of us working in this space cannot expect the human resource and recruitment problem to fix itself.

A solution, to help address this supply and demand issue affecting recruitment, is to educate, encourage and support more sites and clinicians to become investigators and opt into sponsored clinical trial work. The urban corridor houses a finite amount of the pediatric population, leaving a portion hidden from or inaccessible to clinical trial work simply due to their location and/or utilization of an academic or known pediatric research center. There remains a subset of mandated clinical trial work that could be conducted outside of the large, known research centers and the urban corridor. Finding hospitals and clinics with pediatricians and support from their administration to learn and invest resources towards regulatory mandated, industry sponsored research has been difficult, but is a viable mechanism to help this supply and demand issue.

There is no doubt that key stakeholders, including clinicians, pharmaceutical companies, and CROs, need to work together to help develop the next generation of investigators. There is a need for a shift in how clinical research is factored into the clinical care of pediatric patients. We need more pediatric investigators and sites to offer and conduct clinical trials to build knowledge and access more treatment options proven through good research. This includes private practices and general pediatrician clinics, local/smaller community or non-academic hospitals with pediatricians or pediatric units, as well as partnerships with Integrated Research Organizations (IROs).

The first step is educating clinicians. Programs that support and educate on government regulations and industry sponsored clinical trial work during residency and fellowship training can help enable and build a new generation of researchers. Additionally, CROs and pharmaceutical or device companies are needed to support selection of green sites and investigators recognizing that this involves some risk and added support is required to mitigate this risk. Advanced planning is required for this, and collaboration needs to occur well before a clinical trial begins. Clinical trials should be a conversation that is normalized and apart of clinical care but we first must empower and educate pediatricians to feel confident about participation for themselves and their patients. Structures and tools that support new pediatrician investigators may also come in the form of partnerships with larger academic centers, CROs, or IROs that provide smaller hospitals or private clinics access to education, mentoring, and create a pathway to enter and thrive within the industry sponsored clinical trial space.

We have a clear gap where there is a large amount of pediatric clinical trial work to be done and very finite resources to successfully recruit, collect data, and effect pediatric labeling or the sharing of results, so critical to scientific progress. There is a true need to build a new generation of pediatric investigators and sites that capture a more diverse patient pool and allow for trials to successfully enroll in reasonable timelines to impact clinical care.

This article is a call to action for all SOATT members to message, encourage, mentor, and promote the important need

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for new pediatric investigators. Consider what you can do at your own hospital, clinic, or company as a mentor to help develop future researchers and sites. Although the pandemic has had many negative impacts to our lives one major success story is the work researchers have done. Our communities are aware of and talking about industry sponsored clinical trials more than ever and now is the right time to encourage the next generation of investigators. The intention is that this article generates further discussion and willingness of how each of us within SOATT can assist development of sites and investigators to ensure new medicines and innovations are properly and efficiently researched in pediatric patients.

References:


2. FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs: Amendments to Sec. 505B of the FD&C Act Guidance for Industry. May2021 [https://www.fda.gov/media/133440/download](https://www.fda.gov/media/133440/download)


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"Strategies and Readiness (?) for Achieving Therapeutic/Device Development"

Ronald L Ariagno, MD, FAAP

Former Chair of Task Force for Neonatal Perinatal Therapeutic Development (Neo-PeriTD) and Liaison (2016) to Section on Advances in Therapeutics and Technology (SOATT)

Email: rla@stanford.edu

The aim of this article is to reexamine the “final report” on the Task Force for Neonatal Therapeutic Development to the SONPM (January 4, 2021) and to present a proposal to SOATT Executive Committee and membership for further action. Although the Section on Neonatal Perinatal Medicine (SONPM) Executive Committee was not “ready” to pursue this issue further due to other priorities, the experience in attempting to promote regulatory therapeutic (meant to be inclusive of drugs, biologics, devices, etc.) development for neonates has been very instructive. I feel that this history should not be disregarded and more importantly it deserves sincere examination and discussion. Interestingly, the SOATT leadership and membership has a unique advantage since it represents many of the significant stakeholders important to promoting and acting therapeutic development for infants and children. Specifically, my proposal is for SOATT Executive Committee and Membership to review the report, discuss and debate on how to best utilize this template and experience to promote advances in therapeutics and technology under their leadership. As you will read, this quest for me started in 2013 when I was invited to join the Sub-Advisory Committee for Neonatology to the Pediatric Advisory Committee to the Food and Drug Administration (FDA).

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Final Report

The task force was initiated October 22, 2015, for a five-year term. Since the Executive Committee (EC) has decided not to renew, it is appropriate to submit a final report and my resignation as Chair.

Briefly, the mission was to promote and facilitate neonatal-perinatal therapeutics development and FDA regulatory approval for new and established therapies to improve the care and outcome of critically ill newborn infants. The goal was to use the educational, advocacy, liaison, and leadership resources of the AAP and SONPM to establish, through consensus, a culture of regulatory investigation and collaboration for all clinical neonatology practices: academic, corporate, and community based to maximize the opportunity for infants to participate in research and to achieve approval of therapeutics and technology for infants.

There were four working groups (met via phone conferences):

1. Specific Guidelines for Neonatal Therapeutic Development in collaboration with the FDA.
   Co-Chairs: Bob Ward and Mark Hudak (Jon Davis).
2. Facilitate the establishment of an inclusive network of neonatology practices
   Co-Chairs: Brian Smith and Roger Soll
3. Provide Curriculum and funding opportunities for Dual Training in Neonatology Pharmacology and Clinical Trials
   Co-Chairs: Christiane Dammann and Tamorah Lewis (Bob Ward)
4. Promote parent and community advocacy for Neonatal-Perinatal Therapeutics Research:
   Co-Chairs: Mitch Goldstein and Wakako Eklund

Background:

Pre-Task Force

The "Newborn Drug Development Initiative Workshop" was initiated and organized by National Institute of Child Health and Development (NICHD) and FDA in 2003, which met March 29 and 30, 2004 (see Giacoia GP and Mattison DR Clinical Therapeutics 27(6) 796-813, 2005 and 28(9) 1337-1341, 2006) and was primarily focused on the application of Best Pharmaceuticals for Children Act (BPCA) 2002 on behalf of newborns. Of interest Mark Hudak was participant in the Workshop.

The then "Section on Perinatal Pediatrics" (RLA, Chair of the Research Committee) co-funded NICHD-Section Workshop (January 2004), which was jointly organized by RLA and Tonse Raju. Ann Stark the then Chair of the Executive Committee had recommended the Research Committee report on the future research agenda for Neonatology. The Workshop was my response to this request. After some haggling the EC voted to approve co-funding for the Workshop. The summary of the proceedings was published in two articles in Pediatrics: Research in Neonatology for the 21st Century: Executive Summary of the National Institute of Child Health and Human Development–American Academy of Pediatrics Workshop. Part I: Academic Issues (Raju T, Ariagno RL, Higgins R and Van Marter LJ DOI: 10.1542/peds.2004-2556) and Part II: Training Issues (Ariagno RL, Van Marter LJ, Higgins R, and Raju T, MD$ DOI: 10.1542/peds.2004-2559). The articles presented/discussed the regulatory and training issues regarding neonatal therapeutic development. RLA represented SONPM as a participant in the “Pediatric Clinical Trials Stakeholder Forum” planning meeting November 2014.

Overlapping/Concurrent with Task Force

Appointed to FDA (2013-) Neonatology Advisory Committee, which is chaired by Jonathan Davis, Tufts University.

In 2012 The FDA Safety and Innovation Act (FDASIA) was passed, which stated that the sponsor of a drug application must include studies for neonates if scientifically appropriate and the FDA is required to explain the rationale if there is an exclusion.
RLA appointed as representative Neonatologist to the FDA 2013-2015 as Senior Oak Ridge Institute for Research and Education (ORISE was source for funding Federal mandate) Faculty Fellow in Neonatology to help strategize how to facilitate the basic neonatal science research needed to promote the development of drug and new devices for infants. RLA worked six months each year at the main Silver Spring, MD FDA site in the Office of Pediatric Therapeutics and in the Division Pediatric & Maternal Health in the Office of New Drugs in the Center for Drug Development, Evaluation and Review (CEDER). He participated in the Pediatric Review Committee (PERC), which assessed if the Best Pharmaceuticals in Children Act (BPCA) the “carrot” and Pediatric Research Equity Act (PREA) the “stick” were required when new drug applications did not include a Pediatric Study Plan when it was justified to do so. Dr. Lynne Yao, one of my mentors, was Chair of PERC. I continued as Neonatology fellow at the FDA 2015-2017 at 25% (worked 4 months each year at the FDA site) with Intergovernmental Personal Act status 25% FTE to continue initiatives begun during ORISE fellowship and to mentor a new full time FDA Neonatologist, Gerri Baer; continue scholarly projects and collaborative research with the Pediatric Pulmonary Hypertension Network Group and the FDA; participate in pediatric and neonatology relevant meetings at the FDA such as Pediatric Review Committee and International Pediatric Global Teleconference and was available for neonatology consultation when requested. Following the Fellowship, I was a Special Government Employee until 2019. Of note the FDA fellowship was longer than neonatology fellowship 1973-75 at University of California San Francisco and San Francisco Children's Hospital.

The first SONPM Newsletter article, which introduced the need for Neonatal Therapeutic Development by RLA, Mark Hudak and Jon Davis was published in 2014.

The California Association (CAN) provided the first Neonatologists and Neonatal Intensive Care Unit (NICU) Directory in 1994 (funding from Mead Johnson Nutrition) with the leadership of Dilip Bhatt. The AAP Section on Neonatal Pediatrics agreed with CAN to establish a National Directory in 1995. The last Directory in 2011 (updated annually since 1995) included National and Canadian NICUs, Neonatologists and Training Programs. The California Neonatologists, NICUs and Training Program Directory has been kept up to date annually primarily by the efforts of Dilip Bhatt. The National Training Programs has had limited updating for contact information so that the Program Directors in the Organization of Neonatal Training Program Directors (ONTPD) could maintain communication.

The EC under David Burchfield (~2013) decided that the Annual updated Directory, the Chair, Dilip Bhatt (since 1994) and his Committee were no longer needed. Nevertheless, the CA Directory and Training Programs have been updated annually and became a Web Directory in 2020, which was funded by seed money from Stanford followed by grant from Mead Johnson Nutrition. The National Training Program Directory has not been updated since 2011.

No funding for the work of the Task Force was received or requested from SONPM. The California (CA) NICU and Neonatologist Web Directory project (2018-) was accomplished with funds that were obtained independently. Although the SONPM was not interested in facilitating adding the 90 plus national training programs to the CA Web Directory it could have been a robust resource for establishing regulatory research networking and the best way for us to present ourselves to the Institute for Advanced Clinical Trials in Children (IACT) program, which hopefully will have funding to support neonatal regulatory science research.

**What was accomplished:**

**SONPM Newsletter:**
Main portal for providing progress reports to SONPM leadership and members.


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6. Ariagno, RL. Consensus for Standard of Care Practice(s) for NICUs: The Science and the Challenge. Newsletter, Spring 2018.


Journal Articles:


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Commentaries:

A. Ariagno RL. AAP News Volume 36 (2) February 2015 “Workshop focuses on accelerating approval of neonatal therapeutics”  
http://aapnews.aappublications.org/content/36/2/16.2.full.pdf+html


C. Ariagno RL. About Advocating for Parent, Neonatal Nursing and Community support regarding Clinical Trials studies to approve therapeutics for infants. International Neonatal Consortium Newsletter Issue 3, May 1, 2017 (c-path.org see INC program Newsletter).

How publications above related to the four working groups (* indicates also in SOATT Newsletter):

1. Specific Guidelines for Neonatal Therapeutic Development in collaboration with the FDA.  
   1,2,3,6*,8*, I,III,IV,V,VI, VIII, A

2. Facilitate the establishment of inclusive network of neonatology practices  
   7*, 10*, II,VII

3. Provide Curriculum and funding opportunities for Dual Training in Neonatology, Pharmacology and Clinical Trials  
   5, 9*, III

4. Promote parent and community advocacy for Neonatal-Perinatal Therapeutics Research  
   4*, 8*, VIII, IX, B, C

Meeting Presentations:
Recommended and collaborated with Andrew Hopper (District 9 Representative) Program planning Chair in the planning for topics and speakers for a joint session with SOATT on Neonatal Therapeutic Development at National Convention and Exhibition (NCE) Conference in Orlando, Florida 2018.

Planned the 2019 “Cool Topics in Neonatology” Annual Coronado, CA meeting section on Neonatal Therapeutic Development topics, which included “Challenges for Neonatology to Obtain Approval of ‘Off Label’ and New Therapies”, “Importance of method to detect adverse drug events in NICUs”, and “Ineffective Drug Therapies in the NICU” with Mark Hudak as invited speaker.

Funding:
Initial funding was obtained for development of Web Directory from The Division of Neonatal and Perinatal Medicine Chief David Stevenson, which enabled interviewing potential Web Developers and selecting the finalist in 2019, who were willing to start the project with our commitment to seek funding to complete project. The CA Web Directory became active, accessible, and complete in 2020.

Formal proposal to Mead Johnson Nutrition for funding, that we had been discussing with representatives over two years to establish the CA Neonatologists, NICUs and Training Program Web Directory, was submitted by Henry Lee and grant was awarded in 2019.

Other:
Attended annual ONTPD meetings and coordinated with Chairs to keep Therapeutic Development on the Agenda. Invited NICHD Pediatric Trials Network Scientist to present jointly at a meeting to encourage that Program Directors to consider extending training to include Pharmacology and Regulatory Clinical Trial design. Recommended and provided the link for the NICHD BPCA annual online (free) “Principles of Pediatric Clinical Pharmacology and Therapeutics Lecture Series”, which could be available and added to the curriculum for the neonatology fellows in Training Programs each year.
“Strategies and Readiness (?) for Achieving Therapeutic/Device Development”  Continued from Page 13

Reached out to Training and Early Career Neonatologist (TeCAN) to inform next generation of leaders on the importance of consensus for pursuing a neonatal therapeutics agenda in training and practice.


Invited to be liaison (2016) to Section on Advances in Therapeutics and Technology (SOATT) and Co-Chair of Abstract Committee in 2017 and Chair in 2019.


Invited to present Pediatric Grand Rounds “Why Combining Clinical Trials and Regulatory Science is Important” F Edward Herbert School of Medicine, Uniformed Service University, Bethesda, MD, 2017.

Established collaboration with Brian Smith and Daniel Benjamin from the NICHD Pediatric Trials Network (PTN) https://pediatrictrials.org/ on Web Directory Project for support to establish a Neonatal Regulatory Clinical Trials Network. 2018

Western Perinatal Club Briefing Sponsored by the Perinatal Sections of AAP Districts VIII and IX, CAN, and Mead Johnson Nutrition. RLA presented “Challenges for the Field of Neonatology for Approval of “off label” and New Therapies” at Western Society for Pediatric Research Meeting; Carmel, CA, 2018.

Organized FDA visit of Dr. Lynne Yao. Lynne Yao and RLA co-presented Pediatric Grand Rounds at Packard Children's Hospital at Stanford. RLA presented “Challenge for Neonatologists to Obtain Approval for ‘Off Label’ and New Therapies”. Dr. Lynne Yao as visiting Professor from FDA (Director, Division of Pediatric & Maternal Health in the Office of New Drugs and Center for Drug Evaluation and Research CDER) spent the day to meet with faculty interested or involved in regulatory research to be reviewed by the FDA. (2/22/19)

Proposed and delivered/approved update/revision of SONPM Abstract Announcement and Guidelines for submission and for reviewers based on “Essentials for Research Meeting Abstracts” Newsletter, Summer 2019. Regulatory elements were included and called attention to “Methods Research” which describes a method, a device, biomarker or endpoint development from a regulatory perspective. This effort was also used to implement update Abstract platform for SOATT. This project was a response to address Abstract Chairs of both Sections concerns about the need for better guidance for submission to improve quality and better directions for reviewers to improve rigor and inter reviewer consistency.

Review of what was proposed but not done and important to achieve in the future:

Proposed adding all Training Programs in the US and Canada to the CA Web Directory to make the hub for a NICU Regulatory Trial Network in collaboration with the NICHD PTN. Of interest what is new is updating with Web platform. In 1994 RLA was elected Chair of the CAN Organizing Committee, which recommended establishing a Neonatologist, NICU, Training Program Directory to understand our workforce and distribution of care in CA. This information was valuable for the State California Children's Services, who could certify NICUs eligible for MediCAL funds for clinical care. The Organizing Committee wrote the By-laws, which from the beginning, included representation from AAP District 9 on the Board. Mead Johnson Nutrition helped fund CAN, understood the importance of the Directory, and provided funding for yearly publications. In 1995 RLA was elected the first president of CAN and a proposal to establish National Directory was approved by the Section on Perinatal Pediatrics. It is difficult to understand resistance to update and to sustain the Directory, which is critical to know our workforce, distribution of care across the US and the location of training opportunities for prospective neonatology fellows. Up to date information about the regulatory research resources at each site would be key to establishing an effective Neonatal Perinatal Regulatory Clinical Trial Network.

Proposed that SONPM add Neonatal Therapeutic Development to Strategic agenda/plan to promote and facilitate

Continued on Page 15
neonatal-perinatal therapeutics development and FDA regulatory approval for new and established therapies to improve the care and outcome of critically ill newborn infants.

Proposed topics and faculty regarding “Regulatory Research Basics for Neonatologists” to the chairs for the Scottsdale Workshop Meetings for 2018 and 19. This request was in tune with the goal of the Task Force to access the educational resources of the AAP SONPM.

Volunteered to present “Challenge for Neonatologists to obtain approval for off label and new therapies and devices: Call for Leadership” at NCE Section session.

The Development of a “neonatal adverse event severity scale” presents the opportunity to consider offering as MOC part 4 quality improvement study option in the future, which could educate on “how to do” and expand adverse event reporting to all NICUs in the future.

“Scoreboard For the Task Force for Neonatal Perinatal Therapeutic Development (NPTD)” article submitted for Spring 2021 SONPM Newsletter was rejected.

**Conclusion:**

The Task Force has represented the SONPM in collaboration with INC, SOATT (includes FDA and Pharmaceutical representation), March of Dimes, California Perinatal Quality Care Collaborative, California Maternal Quality Care Collaborative, Institute for Advanced Clinical Trials for Children (IACT) and FDA. INC (FDA/Critical Path Institute) is a multi-stakeholder public private partnership and includes global academia, pharmaceutical companies, NIH, regulatory agencies, nursing and parent representation.

Currently, most drugs and therapies used in NICU care have not been FDA approved. We have been using “extrapolation” from other than infant populations to assume safety, dose and effectiveness. We have depended on “expert opinion” and non-regulatory clinical trials.

The Neonatal Drug Development Initiative (NDDI) was 17 years ago. The Task Force over the last five years has promoted the NDDI. The CA Web Directory in 2020 is available and includes NICUs, Neonatologists and the nine Training Programs.

If it is not the time for consensus and leadership for neonatal therapeutic development, when? If not led by SONPM, ONTPD and neonatologists, who?

Why? To improve the care and outcome for critically ill infants, mothers, families and communities that we serve.

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**Update from the Pediatric Trials Network:**

**Addressing Challenges Impacting Public Health in Children**

Rachel G. Greenberg, MD, MB, MHS; Kanecia O. Zimmerman, MD, MPH; Daniel K. Benjamin, MD, PhD

Email: rachel.greenberg@duke.edu

The mission of the Pediatric Trials Network (PTN) is to improve child health via closing the knowledge gap on dosing, safety, and effectiveness information for pediatric therapeutics and devices. The PTN is sponsored by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under the Best Pharmaceuticals for Children Act (BPCA) program, and provides an infrastructure for investigators to conduct studies that improve pediatric labeling and child health. The PTN consists of a clinical coordinating center at Duke Clinical Research Institute (DCRI), a data coordinating center at Emmes, and >200 enrolling sites in 44 states.

Since its inception in 2010, the PTN has contributed to gathering and disseminating information in 18 different...
therapeutic areas (Figure; https://pediatrictrials.org/) A critical part of the PTN’s mission involves working with FDA under the BPCA to perform studies that inform label changes, particularly in drugs that are off-patent. In 2021, label changes for 2 drugs – clindamycin and diazepam – went into effect thanks to efforts by the PTN and its collaborators. Data from 4 different PTN studies contributed to revision of the clindamycin drug label, which was updated to include dosing recommendations for infants with infections. These data are important because the studies found that the doses necessary to reach concentrations of the drug that can kill bacteria change as premature infants become older. For diazepam, PTN pharmacokinetics analysts provided new information regarding how the drug is broken down and how long the drug remains active in the body for pediatric patients between 3 months and 17 years of age. The drug label was thus updated to include these pharmacokinetic data for infants and children with status epilepticus or severe recurrent seizures.

Figure. PTN by the numbers.

Clinical research in children has traditionally presented a number of challenges, and the PTN responded to each challenge via innovation (Table). For example, in response to the challenge of the ever-increasing time, money, and human effort required to start up trials, the PTN has developed several “master protocols”. The PTN’s Anesthetics and Analgesics Master Protocol is a pharmacokinetics, safety, and confirmatory efficacy study of multiple drugs including hydromorphone, ketorolac, ketamine, oxycodone, and morphine. The single protocol allows enrollment of >60 participants per drug, with the same site investigators and study teams involved across drugs. This strategy allows for efficiency in training, contracting, and study execution.

Table. PTN response to traditional challenges in pediatric clinical research.

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<th>Challenge</th>
<th>PTN response</th>
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<td>Limited number of eligible patients</td>
<td>Simplify inclusion/exclusion criteria</td>
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<td>Innovative study design to decrease sample size</td>
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<td>Limited blood volume</td>
<td>Development of new, sensitive drug assays</td>
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<td></td>
<td>Minimal volume sampling methods</td>
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<td>Use of scavenged sampling</td>
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<td>Population pharmacokinetics modeling</td>
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<td>Low consent rates</td>
<td>Production of “lay summaries” to explain research findings</td>
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<td></td>
<td>Sending thank you notes to participants</td>
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<td></td>
<td>Partnering with participant engagement organizations</td>
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<td></td>
<td>Leveraging standard of care procedures</td>
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<td>Onerous contracting and start-up</td>
<td>Development of flexible master protocols</td>
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</table>

Continued on Page 17
Recently, the PTN has turned attention to several special pediatric public health issues where data on drug dosing, safety, and effectiveness is lacking. In partnership with NIH’s INCLUDE initiative, the PTN is helping to address critical health needs for children with Down syndrome. Because individuals with Down syndrome typically have differences in drug response, they are at increased risk for drug toxicity and lack of effectiveness. Currently, no specific guidance exists in drug labels for children with Down syndrome, so clinicians struggle to determine appropriate dosing. The PTN has designed a prospective, multi-center, randomized, placebo-controlled trial of the drug guanfacine for children ages 6-12 with Down syndrome and symptoms of hyperactivity, inattention, and impulsivity. This first-of-its-kind trial will be an important initial step toward accelerating the development of new therapies for children with Down syndrome.

Another important public health issue is the lack of data for neonates exposed to medications via breast milk. PTN’s Safety of Commonly Used Drugs in Lactating Women and Breastfed Infants (CUDDLE) study is a master protocol that is enrolling lactating women who are receiving medications as part of their standard care. During the study, drug concentrations are measured from samples collected from maternal breast milk, maternal blood, and infant blood. This allows pharmacokinetics experts to understand how much of the drug is passed from the mother to the infant during breastfeeding and the effects on infants. Data for the first drug from this study – oxycodone – were recently submitted to FDA for consideration of a potential change to the drug label.

In March 2020, the PTN was the first group to study drugs under an IND that could be used to treat children suffering from acute COVID-19 disease and multisystem inflammatory syndrome in children (MIS-C), and the first group to share that information with FDA for regulatory consideration. The Pediatric Opportunistic Pharmacokinetics Study (POPS), another master protocol study, was updated to include the study of COVID-19 drugs in March 2020, and the first participant enrolled in April 2020. The study collects drug information, biological specimens, and epidemiologic and outcome data for children with SARS-CoV-2 infection. As of February 2022, the study has enrolled >850 children at 39 sites. To extend the impact of this research, the PTN has been engaged in a multi-institution, multi-study collaboration with National Institutes of Health (NIH) called The Collaboration to Assess Risk and Identify LoNG-term outcomes for Children with COVID (CARING for Children with COVID). This collaboration has worked to make de-identified data from children with COVID publicly available, in order to accelerate research on this important topic.

The PTN thus continues to contribute to advancements in pediatric drug development, solving multiple challenges of pediatric trials and completing trials efficiently. Without this important work, clinicians will be forced to guess the correct dosing, and families will have fewer safe therapeutic options. The PTN looks forward to presenting the results of ongoing studies and developing new studies to determine the safest and most effective use of medications and devices in children.

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**iCAN Update - International Children’s Advisory Network**

*Amy Ohmer*

Director, iCAN

Email: amyohmer@icanresearch.org

Spring often brings forth the excitement of planning for many various annual projects. At the International Children's Advisory Network, Inc. (iCAN), through the expertise of our youth members, we are delighted to be a support to many organizations around the world with a focus on pediatric medicine, clinical research, medicine development, and medical device innovation.

In February, iCAN completed the establishment of the iCAN Young Adult Professionals group. This group is for young adults (ages 18 – 25 yo) that want to remain connected to iCAN to continue to participate in leadership activities, mentoring, and also internships.

*Continued on Page 18*
Special congratulations to the newly elected Young Adult Professionals Chair, Rhiannon Perry. Rhiannon will be supporting many new initiatives and helping to guide the founding year of the group. 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.

Most recently, iCAN completed a collaboration between the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT) and our iCAN Youth Members around the world in a special three-part video series. To watch the first iCAN video of young people sharing their experiences within clinical research, please click on this link at https://youtu.be/zDUTUjOhs4. To learn more about the great work from MRCT in supporting children and young people, please visit the iCAN website at: https://www.icanresearch.org/post/ican-youth-members-share-their-voices-in-mrct-center-s-conference-series.

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 discussions on relevant 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 at info@icanresearch.org.
Throughout the next few months, iCAN will be working with the Pediatric Trials Network (PTN.org) to support a new anthology created by iCAN youth members to share their creative work of participating within clinical research trials. Using the prompt: “If you could go back in time to tell yourself what you know now about research, what would you say?”, iCAN youth members will be submitting ideas using short stories, poems, illustrations, electronic art, and original photographs to be included in a book to be shared at the 2022 iCAN Summit. To see all of the projects and opportunities available for kids to participate in, visit this link at https://www.icanresearch.org/open-projects.

Additionally, iCAN collaborated with the eYPAGNet and iCAN Chapters in the US and Barcelona to create the Top 10 Important Points to Engage Young People in Drug Development Activities. To view the video and to share it with colleagues and other stakeholders, visit the link at https://youtu.be/DOGnDMA-2rc.

The ‘iCAN’ Book is now available for purchase at www.icanresearch.org for $25.00 USD using our special Paypal link on the home page under donations. After payment, to receive your copy, please contact us at info@icanresearch.org with your name and mailing address - this beautiful hard-bound book was created by iCAN youth members from around the world and filled with positive statements about overcoming challenges to be the best you can be. Fully illustrated by our KIDS Bari chapter, this beautiful book is a treasure you and your family will enjoy for years to come.

SAVE THE DATE:

• iCAN’s own unique youth series ‘Ask the Experts’ had a new session on Leadership on February 19th, 2022 at 10:00 am EST. To join similar future fun and free events, please register at www.icanresearch.org/events. All are welcome to attend and kids of all ages are invited to join. Additional sessions are open for registration and we welcome all doctors, researchers, and community leaders to join us.

• Join iCAN on June 4th, 2022 at the New Britain Bees Baseball Game by registering at www.icanresearch.org/events. This is a fundraiser event and you do not need to be there to participate - simply donate by purchasing tickets and iCAN will give the tickets to a local child that may not have been able to attend a game. For every $8.00 ticket, iCAN earns $5.00 in donations. All are welcome and we hope to make this a very successful event. Thank you to Dr. Sharon Smith for helping us to support this effort. If you would like to donate or support iCAN, please contact Amy Ohmer at amyohmer@icanresearch.org.

• iCAN will be hosting the annual iCAN Summit from June 11th - June 15th, 2022 in Lyon, France. To learn more about joining, please watch our 2022 Summit video to better understand what iCAN is about. Registration opens on March 15th, 2022 at www.icanresearch.org. This year, the summit will have an emphasis on Rare Diseases with experts joining from around the world. Kids will be able to participate in focus groups, one-on-one discussions, share insights to their own medical conditions and as a week-long project, work on the development of Serious Games, an interactive approach to supporting pediatric patients. We hope to meet our community in-person as this summit marks the first travel experience for our pediatric medical community in over two years. Questions? Donations or sponsorship support are still needed! Email us at info@icanresearch.org and we can help meet your learning needs as well.

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We Need You! 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.
Get ready for the iCAN 2022 Summit Lyon, France!

2022 iCAN Summit
International Children’s Advisory Network

Presented by jumohhealth®

July 11-15th to be held at the University of Lyon, France

Register Today!
www.iCANResearch.org

Join Us In-Person for 2022
Kids - Make Your Summer Count!

- Travel to France
- Share your expert voice
- Shape the future of clinical research
- Support new pediatric innovation
- Engage with global leaders
- Make friends around the world
- Learn about careers in healthcare

• Join iCAN and the American Academy of Pediatrics National Conference and Exhibition from October 7th - 11th, 2022 at the Anaheim Convention Center, Anaheim, California. We can't wait to see you at our booth #2034! Look for the iCAN colors and stop by and say hello!

SAVE THE DATES FOR THE 2022 AAP NATIONAL CONFERENCE IN ANAHEIM, CA!
The Section on Advances in Therapeutics and Technology will have an educational program on Monday, October 10. CHECK https://aapexperience.org/ FOR DETAILS AND UPDATES.
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

(July 2021 to March 2022)

Juliana Aparecida Magalhaes
Leonardo Lins
Ana Cristina Loch
Samana Ali
Amanda Ali
Abbas Hyderi
Alison Faber
Nassr Nama
Katharine Cox
Jessica Garabon
Susan Ellen Kirsch
Felicia Lalos
Zil-E-Huma Sheikh
Daniel Albrechtsons
Laila Pinto Coelho

Patrick Seitzinger
Moustafa Kotb Elmala
Alexandre LeBeaut
Oliver Muensterer
Antonios Makris
Rajiv Arya
Atiqur Khan
Ramya Balasubramanian
Mausumi Ghosh
Saurapratim Ghosh
Duaa Kandooh
Mohammad Almulla
Matteo Calafatti
Mazumi Miura
Joyce Mungu

Victor Wakim
Yew Choy
Marco Carvajal Lopez
Eduardo Velasco-Sanchez
Aurea Rivero
Irene Obuzor
Roberto Somocurcio
Tara Angela Krysteena Dela Cruz
Brian Tiopengo
Hazel Baonga
Furqaan Lim
Moath Alhamad
Khalid Alyafei
Amna Mousa
Alina Abzaletdinova

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<td>Lois Freisleben-Cook</td>
<td>Lawrence Siew</td>
<td>Amielle Smith</td>
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<td>Sheetal Gandhi</td>
<td>David Stitelman</td>
<td>Lisa Winters</td>
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<td>Thiyagu Ganesan</td>
<td>Robert Toscano</td>
<td>Lingie Chiu</td>
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<td>Nicholas Garza</td>
<td>Francesca Joseph</td>
<td>Anthony Recupero</td>
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<td>Shreya Gondi</td>
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<td>Philip Verhoef</td>
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</tbody>
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Soniya Pawar

Neil Copeland
Meredith Garst
Balaji Govindaswami
Hira Unar

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:
Chester J. Koh, MD, FACS, FAAP at ckok@bcm.edu
Byron Alex, MD at btalex@gmail.com
R. Brandon Hunter, MD at rxhunter@texaschildren.org
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Jackie Burke
jburke@aap.org
Section Manager

Mark A. Krajecki
Newsletter Production Specialist