I-ACT FOR CHILDREN
SITE NETWORK - QUARTERLY NEWSLETTER
OCTOBER 2023

Mentorship Program Registration is Open!!!!!

We are excited to announce the 2024 Mentorship Program! The Program is heading into its 4th year and has proven highly successful. The program aims to support and expand the current and next generation of pediatric clinical trial research staff so that high-quality trials can be successfully conducted, medicines can be brought to market with pediatric labeling and children can have safe access to needed therapeutics.

An email detailing the program was recently sent to all Site Network Points of Contact (POCs) and site champions to distribute amongst their institution's pediatric research staff. The email outlines the participation criteria and registration instructions for becoming a Mentor or Mentee. We encourage everyone to take advantage of this invaluable opportunity.

We look forward to working with you in 2024. For more information, please get in touch with the Site Network Team. Here is the registration link for those ready to participate. Mentorship Registration

Legislative Bill - H.R.5269
Pediatric Network Support Act

Check out the new legislation proposed to Congress on August 28, 2023! The bill supports establishing and maintaining a Pediatric Research Site Network, in addition to ensuring healthcare for children is continually improved by enhancing awareness, quality, and support for pediatric clinical trials. We strongly support this legislation. We must continue to improve the process for conducting pediatric research. Surprisingly, despite all of the federal incentives and legislative efforts made over the past decade, there continue to be limited resources to conduct pediatric research and a lag in pediatric drug approval timelines. https://www.congress.gov/bill/118th-congress/house-bill/5269/committees?s=1&r=1

Upcoming Educational Webinars

Enhancing Sponsor and Site Relationships

Leveraging Separate Realities
October 10 @12 pm ET

The current landscape of pediatric therapeutic development reflects the demand for swift-to-market approvals. This reality places pressure on both sponsors and sites to expedite trial development and execution processes. A critical tool for success is a healthy and collaborative site-sponsor relationship.

Please join us as we bring together sponsors and sites to talk openly about their challenges in conducting pediatric trials and potential solutions to these challenges while fostering strong sponsor-site relationships. Together, we can work toward advancing the development and approval of safe and effective treatments for children. Site-Sponsor Registration

Building a Culture of Research
December 5 @ 12 pm ET

Creating a culture of research is imperative to the success of any pediatric research institution. Research culture encompasses our research communities' behaviors, values, expectations, attitudes and norms. It influences researchers' career paths and determines the way that research is conducted and communicated.

For some pediatric research institutions, clinical research is an afterthought. They often have limited funding, little recognition, and/or insufficient support to be successful. We are excited to have sites across our network share how they break through these challenges. They will share with us their efforts in building a research culture and its positive impact on their site. Culture of Research Registration

Welcome to Our New I-ACT Team Members

Vivianna Guzman- Executive Director

Ms. Guzman is our newly appointed Executive Director. She brings extensive experience as a Not-for-Profit association executive providing global strategy, financial and operational leadership over the past 25 years. Ms. Guzman's distinguished career spans other sectors, including public accounting, private equity, consulting, and financial services.

Dr. AJ Allen - Chief Medical Officer

AJ is our newly appointed Chief Medical Officer. AJ is a child/adolescent psychiatrist and a pharmacologist. AJ retired in 2021 from Eli Lilly, where he was committed to developing policies, programs and infrastructure to improve pediatric drug development. AJ played a crucial role in the creation of I-ACT for Children. It only seems fitting that he has come home to be our CMO.

Site Network Portal Update

If you are a registered user of the I-ACT Site Network Portal, please check out the Resources section! If you want to become a registered user, please get in touch with the Site Network Team. We continually add tools,

templates, articles and guidance on various topics to assist with pediatric research. If you have a document you would like to share with the other I-ACT Site Network sites, please let us know – we would love to add it to our growing resource library! You don't want to miss out on these valuable resources. Here is the Site Network Portal public access link. https://iactc.my.site.com/sitenetwork/s/.

Educational Opportunities

News from around the Pediatric Research World-
Now is the Time to Fix the Clinical Research Workforce Crisis

"Perhaps the most visible sign is the widening gap between supply and demand for competent staff. underpinning this is a perfect storm of complex issues. Now reaching crisis point, this problem is far bigger than a staffing issue and ultimately jeopardizes the 'engine' of drug and device development. With the current perilous state of the workforce, proposed enterprise fixes are likely to languish far out of reach, given that even 'business as usual' is under threat. In this article, you will find a brief forensic analysis of the workforce problem and an initial indication of where solutions may lie."

https://journals.sagepub.com/doi/10.1177/17407745231177885

NEW FDA GUIDANCE DOCUMENT

Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors
August 2023

This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and Sponsors in complying with FDA's informed consent regulations for clinical investigations. This guidance supersedes FDA's guidance entitled "A Guide to Informed Consent," issued in September 1998, and finalizes FDA's draft guidance entitled "Informed Consent Information Sheet," issued in July 2014. This document is structured to first present general guidance on the FDA's regulatory requirements for informed consent and a discussion of the roles of IRBs, clinical investigators, sponsors, and FDA related to informed consent, followed by
a series of frequently asked questions.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

SOCRA -Pediatric Clinical Trials Conference 2/21/24 - 2/23/24 - San Diego, California
This conference provides attendees with new information, management tools, and real-life examples to help participants navigate the evolving landscape of pediatric research. SOCRA Conference

WCG MAGI - MAGI@home 10/16/23 - 10/20/23 - Virtual Clinical Research Conference

The WCG MAGI Clinical Research Conference has remained an educational mainstay for clinical trial professionals for over 15 years. MAGI is going virtual this fall, bringing best-in-class, accredited training and education offerings from the comfort of your home or office. https://www.wcgclinical.com/magi/

ACRP - 2024 Conference 5/3/24 - 5/6/24 - Anaheim, California https://acrpnet.org/event/acrp-2024/

Don’t miss the next Site Network Quarterly Call
November 14th @ 12 pm ET

Your Site Network Team

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