Pediatric Clinical Research:
A Vision for Sustainable Site Networks

The Challenge: Patient Enrollment in Pediatric Clinical Research

Patient enrollment, one of the biggest drivers of rising clinical trial costs, is a primary challenge in global pediatric research today. Not only is the available pool of children much smaller than adults, there are ethical and regulatory constraints which significantly limit the number of participants. These limitations are compounded when sites lack the supporting infrastructure needed for robust patient enrollment, when protocols are designed without fully understanding the pediatric arena, and when experienced pediatric trialists are not involved in the process.

Currently there are many networks aligned around therapeutic areas, diseases, and even compounds. Each of these has succeeded or failed for a variety of reasons, yet none has cracked the code of routine patient enrollment and easing the burden of trial administration.

Actually, research infrastructures are getting harder to maintain and site research personnel are stretched too far by competing priorities such as academic studies, NIH requirements, practice management, staffing, training, and career advancement.

The Solution: Sustainable Site Networks

Despite waning resources, the desire and commitment to offer patients the best new treatments and access to cutting edge therapies have increased, making trial participation a priority. Solving enrollment challenges is key to the success of today's trial coordination participants—from pharmaceutical companies and investigational sites to CROs and consultants. Only by working together across business units and competitive boundaries can we create best-in-class protocols, processes, and results that will establish, nurture, and preserve a flourishing and useful network.

Paidion envisions a thriving global community of clinician investigators, pharmaceutical companies, and trial coordination experts committed to working collaboratively using edifying research practices to improve children's health through clinical research.

Paidion will expand on the past successes of pharmaceutical companies who have already invested time, money, and effort in developing their own networks for drugs and classes of drugs, but with one important difference. Because a consortium of pharmaceutical companies will be supporting the network, the network will not dissipate when studies are completed as was the trend when supported by just one pipeline instead of many. Through multi-company collaborations, Paidion will develop and nurture these networks as long-term sustainable communities.

Not only will the consortium provide networks with a continuous pipeline of pediatric trials, it will also provide supplemental resources such as personnel and tools to mitigate site-specific enrollment challenges and ease the administrative burden. Paidion will work with each site to understand their unique challenges to patient enrollment and trial participation and then will create site-specific

mitigation plans to share throughout the consortium. These plans will include resources to be financially supported by the consortium and funded through Paidion via a mechanism appropriate to each institution.

The Outcome: Better Communications, No Redundancy, and Less time and Money

There are numerous advantages to this type of community. Paidion, as the central manager of the networks, will provide one central point-of-contact for each network site as well as overall site management across all consortium projects at that site, regardless of which institution may be coordinating the overall trial. This will enhance communication and standardization across multiple projects and eliminate some of the administrative burden from the site.

If you measure success by the engagement and satisfaction of a broad range of pediatric research physician participants, a good start would be to eliminate redundancies which boost the cost of research but not the overall success of a trial. Some redundancies that are ripe for elimination include:

- specific training costs for physicians and study staff well-vested and experienced in research
- creation and completion of additional regulated and non-regulated trial forms and
- certain trial visits to assess the viability of well-established research sites.

Eliminating these tasks saves time and money for the research sites as well as for pharmaceutical companies. An added bonus of the networks would be to provide professional development. Paidion envisions communities of clinicians and study staff engaged in best practices blogs, web-based trial aids, research FAQs, continuing education, training and more.

The advantages of a paradigm shift to a new type of network with thriving, engaged communities include:

- The consortium is developing trial protocols vetted by network site leaders
- Sites are appropriately resourced to support consortium-sponsored trials
- Paidion has reduced the site administrative burden associated with starting trials by cataloging regulatory document information, standard contract terms, requested ICF template language and IRB meeting schedules as well as by standardizing study forms across multiple sponsors
- Trial costs are streamlined when network investigational sites no longer require pre-study visits, site GCP training, etc. for each trial
- The network communities are routinely included in study publications and actively participate in disseminating trial results

We're excited about the numerous advantages and possible synergies our envisioned Sustainable Site Networks will create. Want to be a part of the conversation? To learn more about our Sustainable Site Networks or to explore joining the community, contact us.