



The PTN Expands its Reach

Making medicine safer for children is a mission that transcends geographic boundaries. The work of the Pediatric Trials Network has recently been aided by the expansion of its studies to other countries. Such international collaboration is advantageous as it gives the network access both to varying patient populations with different maladies and to the input of subject experts from around the world.

In this issue of the *PTN Post*, we cast a spotlight on the individuals, organizations, and clinical sites outside of the United States that are participating in our Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care (POPS) study. Their contributions are helping the PTN to cross borders with its research and make an even greater impact on medical care for children everywhere.

POPS Goes Global

The Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care (POPS) study is both ambitious and unique in that it's characterizing the pharmacokinetics of several off-patent drugs commonly used off-label in children, and it's doing so without requiring the prescription of a single drug. By enrolling only those patients who are receiving the drugs of interest as standard of care and by taking advantage of procedures performed in the course of routine medical practice, this study is minimizing its impact on participants while providing a better understanding of drug exposure in children. The data collected will also provide valuable pharmacokinetic and dosing information for drugs in different pediatric age groups, as well as special pediatric populations (such as obese children). By these measures alone, the implications of the POPS study's findings will be far-reaching in their impact on optimizing drug therapy in pediatrics. With the addition of POPS sites in Singapore, Israel, Canada, and the United Kingdom, the PTN is further broadening its resources and impact.

In the past year, the PTN has nurtured partnerships with institutions and organizations in these various countries in an effort to expand its data pool for studies and foster international relationships to advance pediatric research. The Singapore site at [KK Women's and Children's Hospital](#), for example, emerged out of an existing partnership in [graduate medical education](#) between Duke University (the PTN's home institution) and the National

University of Singapore. The PTN presence in Israel was facilitated thanks to common research interests at the three sites that have expressed interest in the study: Assaf Harofeh Medical Center in Tel Aviv, Hadassah University Hospital in Jerusalem, and Schneider Children's Medical Center in Petah Tikva.



Anne Junker

Access into Canada and the U.K. was facilitated by the cooperation of pediatric research networks within each country that were interested in collaboration to advance the agenda of improving medicine for children. According to Anne Junker, associate professor of pediatric immunology at the University of British Columbia, the issue of off-label use of medications in pediatric populations is a key priority among Canadian authorities. "POPS comes at a time when the Health Canada regulatory agency is undertaking modernization and legislative reform," she observes. "The study format challenges traditional definitions of 'clinical trials' while stimulating the need to consider new ways to supplement important information about the safety of medications used in Canadian populations." As scientific director of the Canadian national [Maternal Infant Child & Youth Research Network \(MICYRN\)](#), Junker played a key role in bringing POPS to four Canadian sites: Hospital Sainte-Justine in Montreal, Manitoba Institute of Child Health in Winnipeg, The Hospital for Sick

A Message from the Lead Principal Investigator



Danny Benjamin, MD, PhD, MPH

Welcome to the eighth issue of the *PTN Post*, your quarterly source for information about the work of the Pediatric Trials Network (PTN).

In this issue, we're looking at how and why the PTN is collaborating with international sites and organizations to advance its research objectives, in this case the POPS study. With the help of groups like the Canadian national Maternal Infant Child & Youth Research Network (MICYRN) and the U.K. National Institute of Health Research Medicines for Children Research Network (NIHR MCRN), the PTN is able to accomplish more in less time and with greater effect. Such cooperation across borders is integral to accelerating the pace of pediatric research and optimizing health care outcomes for kids around the world.

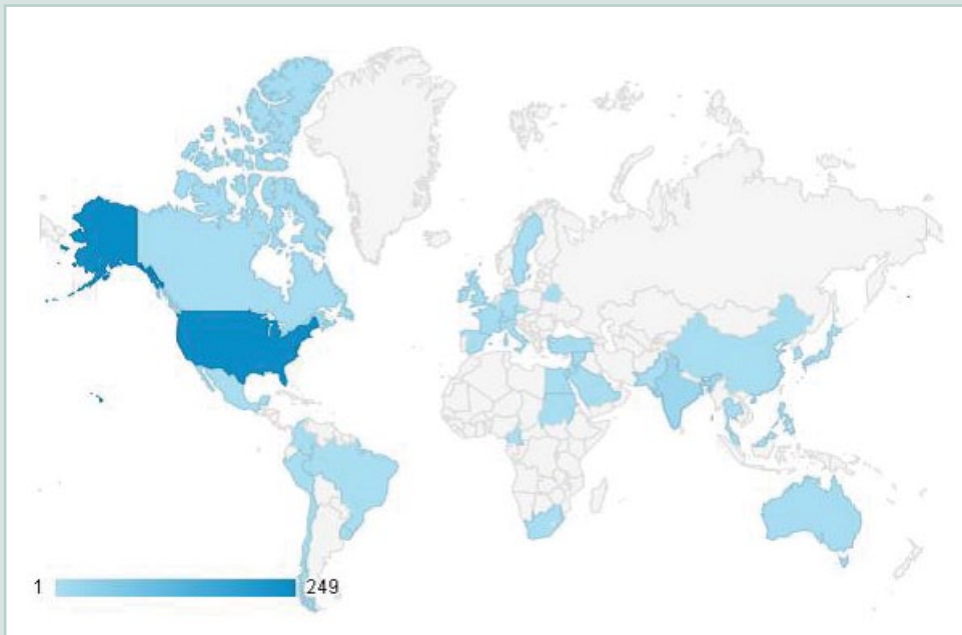
As always, we welcome your input about topics of interest for future issues. Please contact us with your suggestions via the PTN website (<https://pediatrictrials.org/contact-info>).

Children in Toronto, and Children's Hospital of Eastern Ontario in Ottawa. "I believe POPS is the first instance where a single portal of contact with Canada has been made, through MICYRN, to open multiple study sites and coordinate the administrative tasks of contract negotiation and regulatory approval," Junker reflects. "POPS challenges MICYRN, which now joins 20 maternal and child health research institutions in Canada, to 'step up to the plate' and provide this coordinating role."

(continues on page 2)



The PTN Website Reaches an International Audience



Visitors to the PTN website (<https://pediatrictrials.org/>) in January 2014. Deeper shades of blue indicate more frequent visits.

Top 10 Countries Visiting the PTN Website in the Month of January 2014

	Country	Number of Visits
1	United States	249
2	India	23
3	United Kingdom	9
4	France	8
5	Canada	7
6	Australia	6
7	Egypt	5
8	China	4
9	Philippines	4
10	Switzerland	3

POPS Goes Global (from page 1)



Similarly, in the U.K., the PTN was able to tap into existing infrastructure to advance its research goals. As explained by Saul Faust, professor of pediatric immunology and infectious diseases at the University of Southampton and director of the Southampton National Institute of Health Research (NIHR) Wellcome Trust Clinical Research Facility, “The NIHR aims to link the entire U.K. National Health Service into a single research network—meaning that the country’s whole population of 60,000,000 has access to NIHR infrastructure and resources via their local hospitals and primary care services.” Luckily, this pre-existing effort enabled the PTN to readily collaborate with the [NIHR Medicines for Children Research Network \(MCRN\)](#), for which Faust is chair of the Specialty Group Chairs’ Forum. The PTN POPS study is engaging three MCRN sites: University Hospital Southampton, Alder Hey Children’s Hospital in Liverpool, and Bristol Children’s Hospital. Regarding POPS, Faust says, “Investigators and clinicians are keen to

know more about the drugs we prescribe on a daily basis but for which we don’t have really good data on the dose or dose frequency we should use.”

Addressing these critical information gaps is the primary goal of the PTN, which, with the help of these international collaborators, should be able to find answers. “People are genuinely excited by the idea that we can link up research networks across the U.S.A., U.K., Canada, and, in the future, the European Union,” notes Faust. “This academic collaboration will provide a real opportunity to deliver publically funded children’s medicine research faster and with more impact for children.” Junker points out that a lot of the groundwork for such cooperation is already in place: “In years past, MICYRN has established relationships with the U.K.’s MCRN in multiple avenues....POPS extends these collaborative frameworks to the ‘front line’ of clinical studies. By encouraging and facilitating conversations between investigator groups and regulators in the U.S.A., U.K., and Canada, POPS is laying the foundation for future

collaborations that are critically important to be carried out on a global scale.”

To learn more about POPS, visit clinicaltrials.gov. If you’re interested in becoming a site in this or another PTN study, please visit our [website](http://www.pediatrictrials.org).

The Pediatric Trials Network (PTN) is made possible by the Best Pharmaceuticals for Children Act (BPCA). The BPCA, first enacted in 2002, provides mechanisms for studying on- and off-patent drugs in children. Visit us on the web at www.pediatrictrials.org.

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