PEDSnet named key partner in FDA Global Pediatric Clinical Trials Network proposal

With the endorsement of our Steering Board and the PCORnet Pediatric Collaborative Research Group, PEDSnet has been named as a key partner in the Institute for Advanced Clinical Trials for Children (I-ACT)'s response to the FDA Global Pediatric Clinical Trials Network RFP. I-ACT Chairman and President Dr. Ed Connor and team submitted the application earlier this week. The goals of this program are to support the development of the scientific infrastructure needed to plan and execute pediatric clinical trials through collaboration with stakeholders from academia, industry, parent/patient advocacy groups, and government agencies. If funded, with leadership from the Anderson Center at CCHMC and ImproveCareNow, PEDSnet will use improvement methods to assist organizations in meeting trials qualification criteria and to continuously improve trial execution. PEDSnet sites will have the opportunity to participate in the development of a network of clinical sites for future clinical trials. PEDSnet will also lead data analyses using existing EHR, health plan, and registry data for trial feasibility.

Executive Committee supports MOU with the National Evaluation System for health Technology Coordinating Center (NESTcc)

Earlier this month the PEDSnet Executive Committee gave approval to offer a letter of support to the Medical Device Innovation Consortium (MDIC) for their renewal application of the FDA National Evaluation System for health Technology Coordinating Center (NESTcc). Serving as the NEST coordinating center, MDIC asked the PEDSnet Executive Committee, as a prospective strategic partner, to consider formally establishing a relationship between PEDSnet and the NESTcc with a Memorandum of Understanding (MOU). We are pleased to share that the EC voted unanimously to sign the Memorandum of Understanding earlier this week.

PEDSnet CDRN Dashboard

PCORnet. The latest CDRN site level report published by PCORnet can be accessed here. A combined site level report for all CDRNs in PCORnet can be accessed here.

Research Updates

Drexel iFellows Doctoral Award Recipient to Collaborate with PEDSnet
Alex Felmeister, a PhD candidate in Information Studies at Drexel University's College of Computing & Informatics (CCI)

Publications

Medication Safety Article in *Pediatrics* Cites PEDSnet as Innovator
An article in the August 2017 issue of Pediatrics entitled "Methodological and Ethical Issues in Pediatric Medication Safety Research" cites PEDSnet as an example of "Multisite collaborations of hospitals and health systems that agree to share EMR data on child outcomes offer unprecedented opportunities to study the effectiveness of medications and surgical procedures in pediatric populations." Click for abstract and information on obtaining

and Enterprise Informatics lead at the [CHOP Department of Biomedical and Health Informatics](#), recently received the 2017 iFellows Doctoral Fellowship award for his thesis, "Advancing collaborative pediatric brain tumor research through temporally based predictive modeling of a large scale national clinical data research network." Alex will collaborate on the project with PEDSnet (initial pilot with Seattle and CHOP) and The [Children's Brain Tumor Tissue Consortium (CBTTC)](#) to complete his project. [Read more.](#)

Demonstration Study Data Releases
Study data sets have been released and analyses are underway for two PEDSnet demonstration studies. The first is Dr. Jim Franciosi's [Unintended Consequences of PPI Use](#) based at Nemours and the second is Drs. Jason Lang and Tim Bunnell's [Defining Key Determinants on the Path from Obesity to Asthma in Children (KOACH)](#) also out of Nemours.

COMBINE Update
Dr. Peter Margolis and Lisa Boerger of the PEDSnet CCHMC team reported on regulatory and contracting metrics for the [COMBINE trial](#) at the August 11th PEDSnet Executive Committee meeting. On average it took 178 days for participating sites to obtain IRB approval, with 29 days being the shortest time to approval for a single site. Meanwhile, the shortest time to contract execution was 51 days, taking an average of 148 days across sites. Performance metrics will be presented to the EC on a monthly basis to gauge how PEDSnet is doing in relation to other networks, and to identify areas for improvement.

Computable Phenotypes Update
All PEDSnet sites are working diligently on the completion of **chart reviews** for each phenotype cohort, and are on track to meet deadlines for analyses and manuscript submissions.

Data Network Updates
Data Cycles
The PEDSnet [data network](#) is currently live with version 2.5 of the data, and we'd like to thank our sites' informatics teams who have all submitted their version 2.6 data for the upcoming cycle. In July, the network submitted and passed data characterization for [PCORnet 3.1](#). An update to the PCORnet data model included collecting additional labs per their requirements.

full text.

New Publication on LHS Core Competencies
"Development of the Learning Health System Researcher Core Competencies," a research article co-authored by PEDSnet PI Dr. [Christopher Forrest](#) with the [Agency for Healthcare Research and Quality (AHRQ)](#), was published in the August 4th issue of [Health Services Research](#). The article describes the distinguishing features of learning health system researchers and the unique skills needed to be successful. Seven competency domains were identified. [Click](#) for abstract and information on obtaining full text.

PEDSnet Informatics Team Publishes Article on Data Quality
A team of PEDSnet informaticists published an article in the April 2017 issue of the [Journal of the American Medical Informatics Association](#) that "presents a range of data quality issues identified over a period of 18 months and interprets them to evaluate the research capacity of PEDSnet." [Click](#) for abstract and information on obtaining full text.

PCORnet News
NESTcc Selects PCORnet Leaders for Inaugural Governing Committee
Several leaders from [PCORnet](#) have been selected to serve on the inaugural Governing Committee for the National Evaluation System for health Technology Coordinating Center (NESTcc). Read the [full announcement](#).

PCORnet Data Sharing Agreement v2
Thank you! PEDSnet sites all successfully submitted the PCORnet Data Sharing Agreement v2. Our agreements are in the PCORnet queue to be signed. **The PMO will distribute fully executed agreements to sites upon receipt**.

PCORnet Antibiotics Study
Contracting, regulatory, and enrollment metrics for sites participating in the PCORnet Antibiotics and Obesity study are summarized [here](#). Analyses for Aim 2 (growth trajectories) and Aim 3 (maternal-child linkage) are in progress. Two manuscripts, one on cohort description and the other on early antibiotic use and association with pediatric obesity, are being submitted for publication. Abstracts for both papers have been submitted for presentation at the annual meeting of [The Obesity Society](#) in the fall.

CDM Expansion

The data network will begin discussions around **data model upgrades** starting in the fall with the aim to have them implemented in the new year.

QVU Utilization Reminder

Most PEDSnet sites still have many Query Value Units (QVUs) at their disposal (see latest utilization report) and are encouraged to submit query requests to take advantage of the surplus.

PEDSnet Engagement Committee

Since the release of our Spring newsletter the Engagement Committee has finalized their Charter and meeting schedule, piloted a proposal review, and presented their progress to the PEDSnet Executive Committee. The creation of a more robust web presence representing PEDSnet engagement efforts and advertising our suite of services is under way.

Communications Updates

Website User Authentication

PEDSnet leadership, staff, stakeholders, and investigators will soon receive login information for accessing member-only areas of the PEDSnet website. We hope that this web space will become a valuable resource, and encourage members to suggest additions or edits, as well as provide feedback on functionality and design.

PEDSnet Communications Resources

Please click on the links below to view and share up-to-date PEDSnet communications resources:

- PEDSnet One-Pager
- PEDSnet 15-minute Talk
- PEDSnet Data Domains Infosheet

PCRF News

PCRF Names Executive Director

Dr. Rob Califf, Board Chair of the People-Centered Research Foundation (PCRF), announced that **Kathy L. Hudson, PhD**, has joined the organization as Executive Director (please see his 8/16 email update to networks). Hudson most recently served as deputy director for Science, Outreach, and Policy at the National Institutes of Health (NIH). At the PCRF, she joins a team of national leaders in clinical research who established the nonprofit organization to accelerate people-driven research. Click to read the official press release.

PCRF/PCORnet 2.0 Update

PEDSnet Site PIs should be prepared to vote formally on submission of the PCORnet 2.0 sustaining membership application in the near future. PCRF has yet to pinpoint the application deadline but promises plenty of lead time to prepare it. Materials including the PCORnet 2.0 Membership Recommendations and network-specific responses to them are available to review in the meantime.

Pediatric CRG Updates

Research Interest Group (RIG) Prioritization Activities

The Pediatric CRG includes 5 Research Interest Groups (RIGs): Autism, Cerebral Palsy, Epilepsy, Hypertension, and Sickle Cell Disease. Starting **September 15th**, each RIG will be hosting an activity involving the **prioritization of condition-specific research questions**. The activity will be conducted through an online platform that will allow researchers and clinicians to rank and edit the list of research questions in order to set an agenda for future research. If you are interested in participating, please send an email to pedscrg@email.chop.edu.

Melatonin Trial LOI Accepted

We are happy to share that Dr. Forrest and a subset of Pediatric CRG investigators with an interest in sleep health had their LOI entitled **Comparative Effectiveness of Behavioral Intervention and Melatonin Treatment Strategies for the Management of Sleep-Onset Insomnia in School-age Children: A Pragmatic, Randomized, Placebo-Controlled Trial** accepted by PCORI earlier this week. The grant proposal is in preparation.

Website. The PCORnet Pediatric Collaborative Research Group's website is now live. Click to find out more about the CRG's active projects, Research Interest Groups (RIGs), and how to get involved.

Upcoming Events

PEDSnet at the 2017 AMIA Annual Symposium

Levon Utidijian, MD MBI, and a team representing PEDSnet will give an oral presentation at the AMIA annual meeting in November. The presentation, part of a session on *Methods for Developing Clinical Phenotypes* and entitled **"Developing Computable Phenotypes of Pediatric Chronic Conditions in PEDSnet"** will be held on Wednesday, November 8th from 11:42 AM–12:00 PM (room TBD as of this posting).

September 8, 2017 Grand Rounds

Russell Rothman, MD, MPP, Professor of Internal Medicine, Pediatrics, and Health Policy, Vice President for Population Health Research, and Director of the Center for Health Services Research at Vanderbilt University Medical Center will present **"Leveraging Informatics in Pragmatic Research: Initial Experience in PCORnet"** at the 9/8 NIH Health Care Services Research Collaboratory and PCORnet Grand Rounds. Click for full information.

September 22, 2017 PCORnet Best Practice Sharing Session

Dr. Tom Carton, Chief Development Officer for the Louisiana Public Health Institute and Principal Investigator of REACHnet, and Joanna Ball, Digital Community Manager for PCORnet Commons at Genetic Alliance, will present at the 9/22 PCORnet Best Practice Sharing Session **"Leveraging the PCORnet Commons to Engage, Disseminate, and (Hopefully) Transfer Research Innovations."** Click for full information.

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