CPIC eBrief

Congenital and Perinatal Infections Consortium

January 2021

# Director's Message: Moving Forward with Research

I hope everyone is feeling refreshed after the holiday season with family and friends, albeit a socially-distanced one. We are pleased to announce that our Neonatal EV Sepsis natural history study is now active at 19 sites. Congratulations to Cook Children's Hospital (Dr. Susan Whitworth, PI) for enrolling the first subject on the DMID 19-0026-(EVNH) study. We will be following these neonates, who present with clinical signs and laboratory data consistent with viral sepsis, for three months to determine morbidity and mortality, and to explore quantitative changes in the causative virus over time.

In addition, we are finalizing the new Phase I Valacyclovir PK study protocol, and anticipate beginning site selection soon. Recall that only five sites will be selected. If your institution is interested in participating in this study, please contact Jill Griffin to find out what information is needed.

Stay safe and well –
David

Principal Investigator:
David Kimberlin, MD
dkimberlin@peds.uab.edu

Clinical Trials Administrator:
Jill Bailey-Griffin, RN, MSN
jgriffin@peds.uab.edu

Regulatory Administrator:
Susan Branscum
sbranscum@peds.uab.edu

Program Management/Finance:
Sarah Dowdy, MPH
smdowdy@peds.uab.edu

Career Enhancement Administrator:
Melissa McBrayer, MEd
mcbrayer@uab.edu

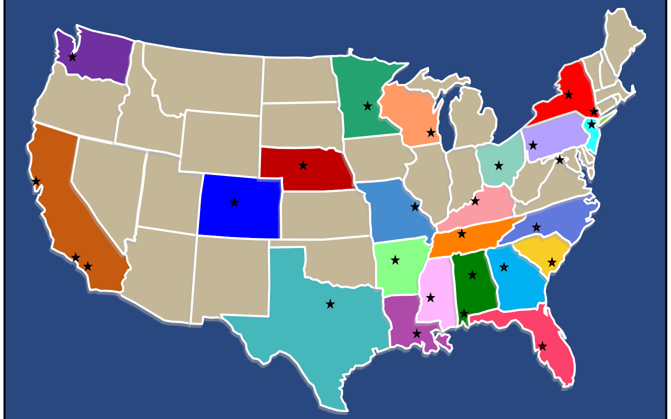
Pilot Program Administrator:
Cheryl Perry, PhD, MPH
cperry@uab.edu

# PAG Partner Profile

Congenital cytomegalovirus (CMV) is the most infectious cause of birth defects, and the leading non-genetic cause of childhood hearing loss, for infants in the United States. Every pregnant woman is at risk of acquiring CMV. And only 9% of women know about it.

A hallmark of the RDCRN is the direct involvement of Patient Advocacy Groups (PAGs). The CPIC PAG is the National CMV Foundation, a nonprofit organization dedicated to preventing pregnancy loss, childhood death, and disability due to congenital CMV. Its programs deliver education to women of childbearing age through digital platforms, strategic partnerships, public health initiatives and grassroots advocacy. It funds early career awards and influences research priorities regarding CMV prevention, treatment and intervention. To advance its purpose, the Foundation supports a policy agenda aimed at ensuring access to prenatal counseling, accelerating research funding, implementing universal newborn screening and advocating for a vaccine. Congenital CMV is common, serious and preventable. Learn more at NationalCMV.org.

## CPIC Research Sites



# CPIC Scholar Program

*On November 11, 2020, we offered our first training opportunity via Zoom. The webinar, titled "Congenital Cytomegalovirus (CMV): The Parent's Perspective," featured presentations by Kristen Hutchinson Spytek and Kathleen Muldoon, PhD – both parents and patient advocates representing the National CMV Foundation (described on page 1). This webinar provided insightful information and perspective to our CPIC Scholars, our pilot recipient, and other CPIC personnel.*

*CPIC Scholar applications are currently being accepted for interested late-stage fellows and early-stage faculty.*

## Links

Rare Diseases Clinical Research Network (RDCRN)

RARE DISEASES
CLINICAL RESEARCH NETWORK

CPIC is supported by the UAB Central Unit located at:
The University of Alabama at Birmingham
Children's Harbor Building, Suite 303
1600 7th Avenue South
Birmingham, AL 35233
1-877-975-7280 or 1-205-934-5316

## Protocol Status

1) The Neonatal EV Sepsis protocol has been activated at 19 sites, with others to come on board as subawards are executed and IRB approvals obtained. There is 1 subject enrolled to date.
2) Our Valacyclovir PK protocol has been reviewed by the DMID, as detailed previously. We expect to finalize this protocol in early 2021.
3) Longitudinal CMV protocol development is a bit delayed, with anticipated study initiation in early 2021.
4) Letermovir PK study design is being discussed ahead of schedule, although study initiation is still anticipated for late 2021, due to the structure of our 5-year budget.

## Administrative and Financial Updates

We are in the midst of the Year 2 budget of our CPIC grant (9/1/20–8/31/21), and we are working diligently to provide updated sub-awards to each site. If you haven't received your draft sub-award, these will be coming to you shortly. We expect Year 2 sub-awards to include funds to continue studies initiated in Year 1. Further into Year 2, we will provide funding amendments to begin the Valacyclovir and Longitudinal CMV studies.

Update on Data Use Agreements – CPIC utilizes REDCap database services through the RDCRN's Data Coordinating Center at Cincinnati Children's Hospital Medical Center (CCHMC) for its Neonatal EV Sepsis study. CCHMC intends to establish a Data Use Agreement (DUA) with each site to formalize this transfer of data. However, the CCHMC DUA template and process is undergoing revisions at this time. If your site has not yet established a DUA with CCHMC, please watch for updated DUA information and a request in the future.

## CPIC to be Featured in Upcoming RDCRN Newsletter

Watch for a feature article on CPIC in an upcoming RDCRN *Spotlight on Rare Diseases Newsletter*. This e-publication was designed to enhance communication among those interested in the treatment and cure of rare diseases. They are interested in feedback and suggestions for future issues, so please send any comments to rd.dmcc@cchmc.org. To subscribe to the newsletter, click here.

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