

Director's Message: Grant Review and Closeout

As you know, our CPIC renewal grant was submitted in August and is awaiting Scientific Merit Review. The initial timeline had our review scheduled for February and the Advisory Council Review in May. This would have meant receiving feedback on our application by May or June. However, the recent suspension of NIH study panels has delayed this timeline. We recently heard that our original study section will be reviewing our application and that our review dates are currently set for early May. It would be ideal for this review to occur prior to the June trans-NIH Council meeting, so we are hoping that these most recent dates hold. If we score well, we should have a reasonable trajectory toward continuous funding, however, it is possible changes could occur prior to our review. We will keep everyone posted as we receive additional information on this process.

Currently, we are continuing to focus on completing the studies that are ending with this grant cycle. This includes completing visits, cleaning databases, and preparing final reports and manuscripts. We will need your help with each of these activities, so please pay special attention to requests as we finish out grant Year 5.

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<u>Pilot Program Administrator:</u> Cheryl Perry, PhD, MPH <u>cherylperry@uabmc.edu</u> Stay safe and well – David



CMV Foundation News

June is CMV Awareness Month! The <u>Strides 4 CMV Worldwide Virtual</u> <u>5k</u> is happening on June 28th. Join us and register <u>here</u>!

For families, the National CMV Foundation is partnering with Moderna and RTI Health Solutions to learn more about experiences with congenital CMV. We want to learn about the burden of caring for a child (aged 0-17 years) with congenital CMV, including how it affects quality of life, work, and the costs associated with caring for your child. To see if you are eligible to complete the survey(s), please visit this <u>link</u>.

If you are a mother of an infant who is under 6 months of age and has a confirmed congenital CMV infection, you may qualify to participate in the CUBS Study sponsored by the University of Michigan. Through this study, researchers hope to gain a better understanding of development in infants with congenital CMV to develop better support and interventions in the future. Participants will complete online questionnaires at various time points and will be compensated. To see if you qualify, visit <u>here.</u> You can also contact the study team via email <u>here.</u>



Clinical Trials Day is May 20th

We are looking ahead to May 20th - Clinical Trials Day! This date marks the 1747 experiment by James Lind, a British naval surgeon, who conducted one of the first recorded clinical trials to study scurvy treatments. Using just 12 sailors, he discovered that citrus fruits could cure the disease—an insight that greatly improved the health of the British fleet. Lind's story, though over 250 years old, resonates with today's clinical researchers. We hope all CPIC Scholars and investigators will celebrate Clinical Trials Day as a sign of hope and inspiration to those committed to advancing medical science. For those interested in the CPIC Scholar program, please contact Melissa McBrayer or visit https://cpic.rarediseasesnetwork.org/fundingopportunities/scholar-awards.

Links

Rare Diseases Clinical Research Network (RDCRN)



<u>CPIC is supported by the UAB Central Unit</u> located at:

The University of Alabama at Birmingham Children's Harbor Building, Suite 303 1600 7th Avenue South Birmingham, AL 35233 1-205-638-2530

Administrative and Financial Updates

We are half-way through the final budget year for this grant which ends 8/31/25. Please invoice for Year 5 maintenance funds and for any completed subject visits. If you have any questions about invoicing for subaward agreements, please direct them to Sarah Dowdy (sdowdy@uabmc.edu).

Data Hosting Agreements Required for EV Sepsis and Retrospective CMV Studies – CPIC utilizes REDCap database services through the RDCRN's Data Coordinating Center at Cincinnati Children's Hospital Medical Center (CCHMC) for these studies. Questions about the DHA should be directed to rd.dmcc@cchmc.org.

Protocol Status

1. The Neonatal EV Sepsis protocol v3.0 (6/27/23) completed enrolment on 3/1/25, with 57 subjects enrolled in Arm 1 (the main study) and 10 in Arm 3 (deceased subjects). We are now in the study data clean-up process.

2. The Valacyclovir PK protocol v4.0 (3/5/24) has been activated at 10 sites. Group 1 enrolled 15 subjects and included 8 with full PK data. Enrollment is open for Group 2 subjects at the higher dose. The first Group 2 subject was enrolled on 3/20/25 and 7 additional subjects are needed before enrollment ends on 6/30/25.

3. The Retrospective/Longitudinal cCMV protocol v3.0 (3/24/23) is active at 25 US sites and 2 UK sites, with 88 enrolled. Half of those enrolled have asymptomatic infection and half have symptomatic disease. Study enrollment ended on 3/31/25.

4. The Letermovir PK protocol v3.0 (10/23/24) is active at all sites with 2 subjects enrolled. Sites are encouraged to actively work with their clinical teams to identify subjects that are eligible for the study.

CMV Family Database 2025

Participation in this database provides information to researchers in the areas of diagnostics, treatment and prevention of CMV. It also allows the National CMV Foundation to connect researchers with newly diagnosed families and those interested in working on CMV advocacy. Sign up <u>here</u>.