



## Director's Message: Annual Meeting & Competitive Renewal

We are looking forward to seeing folks this week at the CPIC Annual Meeting at IDWeek! We will review the current status of our ongoing studies and give overviews of what we have proposed for our next 5-year funding cycle. In addition to the Phase I oral Letemovir study, we have proposed three new research projects including: 1) a retrospective longitudinal natural history study to assess the evaluation of neonates with suspected CS, to develop and validate an Artificial Intelligence tool to improve diagnostic evaluation; 2) an adaptive Phase Ib/IIa pharmacokinetic, virologic, and safety assessment of a loading dose followed by maintenance dosing of Pleconaril in neonates with viral sepsis caused by EV; and 3) a Phase I adaptive, escalating single-dose and multiple-dose pharmacokinetic and safety assessment of the HSV helicase-primase inhibitor IM-250 in infants with neonatal HSV disease. The renewal grant is at the NIH now, but it won't be until 2025 before we hear about the study section review and funding possibilities. We are very hopeful though, for continued opportunities for our Consortium! Your leadership within the network not only is making our studies better, but it also is impacting the lives of children – which of course is why we do this in the first place. Thank you!

Stay safe and well –  
David

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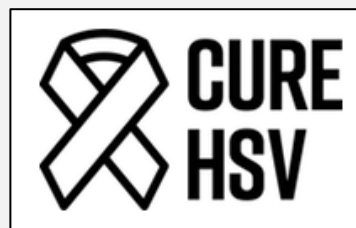
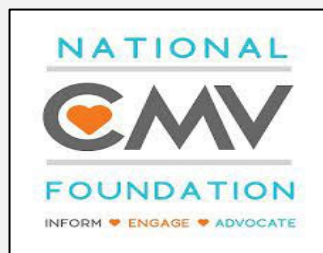
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## CMV Foundation News

Neonatology Today published three articles discussing CMV screening in newborns, with several [National CMV Foundation](#) leaders including: Board President, Mary Uran, MPH, Executive Director, Dr. Khaliah Fleming, Immediate Past President, Dr. Megan Pesch, and Scientific Advisory Committee Co-Chair, Dr. Mark Schleiss. The article states, "The era of cCMV screening is here! Of the cCMV screening options before us—universal, targeted, expanded targeted, or none-of-the-above—the only alternative that is not acceptable is “none-of-the-above.” Even when confronted with uncertainty in prognosis and long-term outcomes, parents prefer to have the knowledge that their infant has a cCMV infection. You can read the articles [here](#)."

Check out the [CMV Speaks Podcast](#) recent episode featuring Tom and Carol Vereecke, who share their granddaughter's cCMV diagnosis and motivation to launch their own CMV fundraiser, [Cycling for CMV Awareness 55](#). Tune in to hear them provide updates about their granddaughter and their cycling plans, which will continue through 2026! You can listen to the episode [here](#).



## Administrative and Financial Updates

Our 4<sup>th</sup> budget year ended 8/31/24. Please invoice for Year 4 maintenance and subject visit funds. UAB received the Year 5 Notice of Award. Subaward amendments will go out to sites soon. If you have any questions about invoicing for subaward agreements, please direct them to Sarah Dowdy ([sdowdy@uabmc.edu](mailto: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](mailto:rd.dmcc@cchmc.org).

## CPIC Scholar Update

Scholars attending IDWeek have the opportunity to gather for coffee and conversation with Dr. James Willig, Scholar Program Director, and CPIC co-PIs Drs. Kimberlin and Hobbs. They will also be able to hear from the 2023 CPIC pilot awardee, Dr. Monika Dietrich, who will present the results of her research at the CPIC Annual Meeting held on 10/18 from 12-2pm (PDT). She will also present to the RDCRN Career Enhancement Committee on 11/18 at 11am (CST).

Contact Melissa McBrayer for more information on the Scholar program or visit <https://cpic.rarediseasesnetwork.org/funding-opportunities/scholar-awards>. Scholar applications are received year-round.

## Links

[Rare Diseases Clinical Research Network \(RDCRN\)](#)



CPIC is supported by the UAB Central Unit located at:

The University of Alabama at Birmingham  
Children's Harbor Building, Suite 303  
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## Protocol Status

1. The Neonatal EV Sepsis protocol v3.0 (6/27/23) is active at all 31 sites, with 55 subjects enrolled in Arm 1 (the main study) and 8 in Arm 3 (deceased subjects).
2. The Valacyclovir PK protocol v4.0 (3/5/24) has been activated at 10 sites. Others are encouraged to submit ICFs and site activation documents to the UAB CU. It has 15 subjects enrolled, and 8 with PK data collected. Enrollment is currently halted until the Group 1 PK results can be analyzed. The SMC will meet in November to review the PK and safety data and will decide on study continuation.
3. The Retrospective/Longitudinal cCMV protocol v3.0 (3/24/23) is active at 21 sites, with 49 enrolled. NIAID wants this study completed by August 2025, so we need sites activated and enrolling. Submit tracked ICFs and context documents and complete training ASAP. We are actively working to activate sites in the UK to increase enrollments.
4. The Letemovir PK protocol v2.0 (2/13/24) is active at 9 sites (0 enrolled). Others are encouraged to submit ICFs and site activation documents to the UAB CU. We are revising the protocol to expand the age of enrollment for subjects, aligning it with the current Redbook recommendations for treating moderate to severe CMV patients.

## Annual Meeting Reminder

Hope to see everyone at the CPIC Annual Meeting which will be held in conjunction with IDWeek on 10/18 from 12-2pm in the JW Marriott LA Live Gold Ballroom 1.

[PROVIDE FEEDBACK](#) | [CONTACT](#)