



## Director's Message: EAC Updates and New Pilot Recipient

Our second External Advisory Committee (EAC) meeting, held May 9th, provided advice on current projects (i.e., how to increase Enterovirus study enrollment and how to improve recruitment/retention for the Valacyclovir and Letermovir studies) and future opportunities (e.g., new collaborations; other diseases; consideration of antiviral therapies such as Maribavir, new antivirals or monoclonals; and use of cytotoxic T-lymphocyte therapies). We greatly appreciate their guidance. I also want to announce our newest CPIC Pilot awardee – Monika Dietrich, MD, an Assistant Professor of Infectious Diseases at Tulane University. Her project, entitled *Early postnatal cytomegalovirus infection in infancy and gastrointestinal manifestations*, will allow her to study whether early postnatal CMV infection increases biomarkers of intestinal damage and inflammation, and results in impaired responses to oral rotavirus vaccine in Sierra Leone. We wish Dr. Dietrich success as her research progresses! Finally, I want everyone to be aware that we have planned a CPIC working lunch during IDWeek on October 14<sup>th</sup> from 11am-2pm in the Westin Boston Seaport District Hotel. I look forward to seeing you there!

Stay safe and well –  
David

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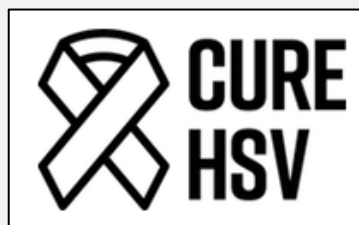
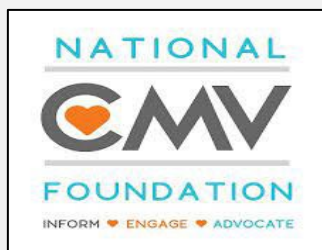
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## CMV Conference and HSV Research

The 2023 congenital CMV Public Health and Policy Conference will be held in Salt Lake City, Utah, October 8-10. Its goal is to present the latest diagnosis and treatment research, raise awareness, delineate prevention efforts, provide information about early intervention, and disseminate family support resources to reduce the number of babies born with CMV. It also seeks to connect families affected by CMV with the resources they need to improve their quality of life. More information is available here: <https://cmv.usu.edu>.

Also, Herpes Cure Advocacy is celebrating a step forward on its path to cure, treat and prevent Herpes. The NIH assembled a Multi-Council Working Group for HSV and requested input from scientists and the public to develop a strategic plan. Led by NIAID, the Working Group also includes five other Institutes. Its strategic research plan is structured around four priority areas: 1) improving knowledge of HSV biology, pathogenesis and epidemiology; 2) accelerating research to improve diagnosis; 3) improving strategies to treat and cure HSV; and 4) advancing research to prevent HSV infection. Advocates see this response by the federal government as an important win.



## Protocol Status

- 1) The Neonatal EV Sepsis protocol is active at 29 sites, with 23 subjects enrolled. It is being amended to v3.0 (6/27/23) and will be sent out following IRB approval.
- 2) The Valacyclovir PK protocol v3.0 (8/9/22) has been activated at 6 sites. Others are encouraged to move forward expeditiously, by submitting ICFs and site activation documents, and by completing training ASAP.
- 3) The Retrospective cCMV protocol v3.0 (3/24/23) was approved by the sIRB and is now active at 2 sites. Others are encouraged to gather regulatory documents, submit tracked ICFs and local context documents, and complete required training ASAP.
- 4) The IND for the Letemovir PK protocol v1.0 (2/13/23) was given an FDA safe to proceed notification on 4/28. Site selection was completed 3/15 and we anticipate the study start-up meeting will occur by September.

## CPIC Scholar Circle

*The CPIC invites applications to its Scholars Program. The CPIC Scholars Program is open to interested fellows and early-stage faculty conducting mentored research related to congenital and perinatal infectious diseases. Scholars may request CPIC funds to attend meetings or participate in a mini-sabbatical research experience. The application is brief.*

Visit

<https://cpic.rarediseasesnetwork.org/funding-opportunities/scholar-awards> for more information.

## Administrative and Financial Updates

Current subaward agreements now span 24 months for “Year 3” (which runs from 9/1/21 to 8/31/23). Please bring invoicing up-to-date for maintenance funds and subject fees for this timeframe. If you have any questions about this process, they should be directed to Sarah Dowdy ([sdowdy@uabmc.edu](mailto:sdowdy@uabmc.edu)).

Data Hosting Agreements Required for Enterovirus Sepsis Study and Retrospective CMV Study – CPIC utilizes REDCap database services through the RDCRN’s Data Coordinating Center at Cincinnati Children’s Hospital Medical Center (CCHMC) for these studies. Check [here](#) to see if your site has an executed Data Hosting Agreement (DHA) with CCHMC. Questions about the DHA should be directed to [rd.dmcc@cchmc.org](mailto:rd.dmcc@cchmc.org).

## Links

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



CPIC is supported by the UAB Central Unit located at:

The University of Alabama at Birmingham  
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## Visit CPIC’s Website

When you get a chance, please check out the content on our website: <https://cpic.rarediseasesnetwork.org/>. Use the top navigation bars for information on our research, our patient advocacy groups, resources for researchers and clinicians, resources for early stage investigators, and more. Our revamped site is now more user friendly, with a focus on information that is most useful to lay audiences. If you have any feedback or suggestions for additional content, please contact Cheryl Perry ([cherylperry@uabmc.edu](mailto:cherylperry@uabmc.edu)).

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