



Director's Message: Research and Upcoming EAC Visit

I hope everyone has weathered the storm of COVID-19, flu, and RSV season. We continue to prepare for our second External Advisory Committee (EAC) meeting in early May, so if you have suggestions related to it or to the upcoming competitive renewal application, please let me know. We will keep you updated on what we learn during the visit and how it may shape our plans moving forward. We continue to make progress on our CPIC research projects, with 2 of 13 sites activated for the Valacyclovir study and 21 subjects enrolled in the Neonatal EV Sepsis study. A pre-IND has been submitted to the FDA for Neonatal EV Sepsis to get feedback on amending it to include data from subjects who died from enterovirus/ parechovirus prior to their participation in the study. We are also pleased to report that the IND for our Letemovir PK protocol v1.0 (2/13/23) was submitted to the FDA on March 22nd. Barring any FDA holds, we anticipate this protocol being finalized 30 days post IND submission. Site selection was completed on March 15th and the DMID is reviewing the need for site assessment visits by the monitoring team. I'm proud of our progress and confident there will be more to come!

Stay safe and well –
David

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CMV Public Health and Policy Conference: Save the Date

The 2023 congenital CMV Public Health and Policy Conference (CMV-PHP) will be held in Salt Lake City, Utah, October 8-10. The goal of the conference is to present the latest research on diagnosis and treatment, raise awareness, delineate prevention efforts, provide information about early intervention options, and disseminate family support resources in an effort 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.

This is a fantastic conference with the latest information for parents, physicians, researchers, allied health professionals and more. Additional information can be found here: <https://cmv.usu.edu/> and registration will be open on or around May 10th. Information related to registration fees can be found here: <https://cmv.usu.edu/registration/participants.cfm>. Other questions should be directed to info@cmvconference.org.

With your help, we can reduce the number of babies born with CMV!



Protocol Status

- 1) The Neonatal EV Sepsis protocol v2.0 (8/11/22) is active at 29 sites, with 21 subjects enrolled. We encourage sites to continue promoting this study.
- 2) The Valacyclovir PK protocol v3.0 (8/9/22) has been activated at 2 sites. Others are encouraged to move forward expeditiously, by submitting ICFs and site activation documents, and by completing training ASAP.
- 3) The Longitudinal CMV protocol v3.0 (3/24/23) is under review by the sIRB. This version clarifies that only subjects treated with Valganciclovir and/or Ganciclovir are eligible to participate. Sites are encouraged to gather regulatory documents and complete training.
- 4) The IND for the Letemovir PK protocol v1.0 (2/13/23) was submitted to the FDA on 3/22. Site selection was completed 3/15 and we anticipate that the study start-up meeting will occur in mid-May.

CPIC Scholar Circle

The Scholars Circle will meet in May to learn about advocacy with Coalition of Patient Advocacy Groups representative, Kristen Hutchinson Spyttek. Kristen is the president and co-founder of the National CMV Foundation, a patient advocacy group aimed at preventing pregnancy loss, childhood death, and disability due to congenital CMV. Through this question-and-answer session, Scholars will learn more about the advocate's perspective and consider their own beliefs and practices related to advocacy. A follow-up session with an established physician and advocacy champion will follow in June.

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).

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.

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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CPIC Scholar Kudos

Congratulations to Baoming (Benjamin) Liu, PhD, for having his abstract (*Genetic diversity and conservation of VP1 gene of human enteroviruses*) accepted for the RDCRN's spring meeting. Dr. Liu is assistant director of the Microbiology Laboratory and the Infectious Disease Molecular Diagnostics Laboratory of Children's National Hospital and an assistant professor of Pathology, Pediatrics and Microbiology, Immunology & Tropical Medicine at the George Washington University in Washington, D.C. His research mentor is Roberta DeBiasi, MD.

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