



Director's Message: External Advisory Committee Feedback

Our first meeting with the CPIC External Advisory Committee (EAC) was held on March 2nd. It was a very productive 2-hour meeting that included EAC members, NIH representatives (*ex officio*), and the CPIC Executive Committee. After brief presentations on our activities, the EAC discussed ways to grow and improve our consortium. For CPIC research, they suggested expanding the cohort for the longitudinal CMV study to include those who were treated for congenital CMV for a standard duration but outside the confines of the CASG clinical trial. They felt it was especially important to recover time lost due to the COVID shutdown. The EAC also suggested expanding CPIC reach by using remote consenting/visits or by adding investigators, especially in the midwest and mountain west. To share and promote research findings in a public-facing format, they urged continued involvement with the National CMV Foundation and suggested we work with them to contribute to population-based newborn screening efforts for CMV. For future areas of research, the EAC mentioned Hepatitis C and using PK data modeling for efficient drug development. It was also noted that PK modeling or the CPIC biorepository could be useful for future pilot studies or projects led by junior investigators. We greatly appreciate this guidance and will be mindful of these suggestions as we move forward.

Stay safe and well –
David

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Updates National CMV Foundation Activities

The National CMV Foundation is pleased to share the article, "[Cytomegalovirus Affects More than Hearing](#)," published by The American Speech-Language-Hearing Association. It is co-authored by CMV mom and Speech-Language Pathologist, Lisa Eickel, who also serves as a CMV Community Alliance Chair for the National CMV Foundation. The article calls for more education and research on—and communication sciences and disorders treatment attention to—the long-term physical and developmental consequences of congenital CMV. One consequence is Late Onset Hearing Loss (LOHL). The National CMV Foundation is proud to be participating in [LOHL Awareness Week](#), which runs from May 4-10.

Finally, the National CMV Foundation is accepting applications for its [Early Career Research Award](#)! This \$50,000 award funds innovative research related to maternal or congenital CMV infections. Early career researchers including mentored pre- and post-doctoral trainees or junior faculty who have not been a PI on an NIH grant may apply. The deadline for online submission is 11:59pm EST on May 31st.



Protocol Status

- 1) The Neonatal EV Sepsis protocol is active at 28 sites, with 4 subjects enrolled. We ask all activated sites to keep working with their virology labs and neonatology teams to identify possible subjects for enrollment.
- 2) With FDA feedback, we are revising the Valacyclovir PK protocol and working with the NIH to resubmit the IND later this month. After submission, the FDA has 30 days to provide additional feedback. We anticipate initiating this study during the fourth quarter of 2022.
- 3) The Longitudinal CMV protocol is under review by the NIH and the DMCC. We anticipate study initiation in the summer of 2022.
- 4) Letemovir PK study design has been reviewed by the DMID Clinical Science Review Team. We have initiated development of the full protocol and ICF and anticipate study initiation toward the end of 2022.

CPIC Seminar Series

The next CPIC Seminar, "Pharmacokinetics in Drug Development," will be presented by Edward P. Acosta, PharmD, on Friday, May 20th at noon (CDT). Dr. Acosta is Professor of Clinical Pharmacology and Toxicology; Director of the Division of Clinical Pharmacology; and Director of the Pediatric Pharmacology Laboratory (PPL). The PPL and Dr. Acosta's expertise are essential for CPIC research as a collaborator for Phase I investigations of drugs.

Friday, May 20th 12:00 pm (CDT)

<https://uab-mc.zoom.us/j/82751209216?pwd=d3BKVUtCNXREeDdtNW04ODISZ1ZpQT09>

Mtg ID: 827 5120 9216; Passcode: 347930

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
1600 7th Avenue South
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1-877-975-7280 or 1-205-934-5316

Administrative and Financial Updates

The NIH has announced that the next RDCRN Grant Funding Cycle will begin 1 year later than previously expected. This means that CPIC has the opportunity to take a no cost extension, extending our funds (and work) into a 6th year. CPIC intends to apply for the no cost extension, moving our grant end date to 8/31/25. We expect to have adequate funds for our CPIC sites in Year 6, considering the pandemic-related slowdowns we experienced in Years 1 and 2.

Please invoice for maintenance funds and subject fees provided in your Year 3 (9/1/21-8/31/22) subawards. If you have any questions about this process, direct them to Sarah Dowdy (sdowdy@uabmc.edu).

Data Hosting Agreements Required for Enterovirus Sepsis Study – 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. Your site should have received a Data Hosting Agreement (DHA) request from CCHMC. This agreement is between your institution and CCHMC. Direct any questions about the DHA to rd.dmcc@cchmc.org.

Why Apply to be a CPIC Scholar?

Scholar designation provides access to funds for travel to meetings, funding for mini-sabbatical experiences, and training opportunities through CPIC and the larger NIH Rare Diseases Consortium Research Network. Visit <https://rdcrn.org/cpic/scholars> for the 2022 RFA and contact Melissa McBrayer (mmcbrayer@uabmc.edu) with questions.

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