Director’s Message: RPPR Accomplishments

In our initial RPPR, submitted for the 7/1 deadline, we reported extensive involvement with the Data Management and Coordinating Center (DMCC) including their agreement to use our Neonatal EV Sepsis natural history protocol to pilot test how the Cincinnati Children’s Hospital Medical Center IRB might serve as the single IRB of record for Rare Diseases Clinical Research Network (RDCRN) sites. We also worked with the DMCC to explore the possibility of developing and leading an International Congenital CMV Registry and to develop online content for the RDCRN website.

In addition, we agreed to process samples for the RDCRN Primary Immune Deficiency Treatment Consortium to assist with their study of CMV in neonates with severe combined immunodeficiency, and we shared our EV Sepsis Natural History protocol with the Phenylalanine Families and Researchers Exploring Evidence (PHEFREE) Consortium as an example of how to write a longitudinal natural history and outcomes study. Going forward, we will continue to work to add value to the Network.

Stay safe and well –
David

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COVID-19 Update

Though we are continuing to work on Consortium activities, as detailed in this eBrief, many of us are still working remotely at least part-time and connecting by Zoom or WebEx to communicate. We now have 14 sites with executed subawards for our Neonatal EV Sepsis protocol, with 4 activated to enroll and 10 having IRB pending. Fourteen other sites are still in the process of establishing their subawards.

After a slight delay related to COVID-19, we also posted our call for CPIC Scholars and Pilot and Feasibility Project pre-applications on May 22nd. We have requested full pilot applications from three individuals and continue to seek additional CPIC Scholars for our virtual training opportunities. We plan to have a group of CPIC Scholars and our inaugural pilot recipient named by September 1st. We also hope to begin enrolling subjects in our Neonatal EV Sepsis study soon, at least in areas that are less impacted by the COVID-19 pandemic.
Protocol Status

1) The Neonatal EV Sepsis protocol has been activated at 4 sites, with others to come on board as subawards are executed and IRB approvals obtained.

2) We have received the GlaxoSmithKline PK database for our Valacyclovir PK protocol and have identified our mechanism to purchase the study drug. We plan to initiate this study by October of 2020.

3) Longitudinal CMV protocol development is a bit delayed, with anticipated study initiation in late 2020.

4) Letermovir PK study design is being discussed ahead of schedule, although study initiation is still anticipated for late 2021, due to the structure of our 5-year budget.

Administrative and Financial Updates

We are nearing completion of our first year on August 31, 2020! Nearly all sites have established subawards, officially securing their membership in the Congenital and Perinatal Infections Consortium. We’d like to have all sites fully on-board before our grant year is out.

Sites should consider... Have you been activated to enroll in a CPIC study?
– If NOT YET! Please check to see what subaward, IRB, and regulatory items are still pending.
– If YES! Please be sure to invoice for your site’s start-up costs and any enrollment costs.

Reminder – Since CPIC will utilize Cincinnati Children’s Hospital Medical Center (CCHMC) REDCap database services for the Neonatal EV Sepsis study, sites should work to establish a Data Use Agreement (DUA) with CCHMC to formalize this process. Draft DUAs will be provided by the UAB Central Unit in conjunction with each site’s Enterovirus subaward/amendment. Also, please note that we will be using a DMCC-provided tool for our eRegulatory binder. More information will be provided in the coming weeks about this system.

CPIC Logo Design Completed

With the help of a graphic designer at the CCHMC, we recently completed development of the CPIC logo. The color was based on information presented in the Impact of color on marketing (Singh, 2006), which indicated that blue denotes calmness, reliability, safety and tranquility. The graphic includes a shield protecting a mother and infant from viruses circulating outside. Check it out in the header of this eBrief.