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Emmes-Supported Study Results in the First Pediatric Drug Labeling Change for 2019

The Best Pharmaceuticals in Children Act Integrates NIH and FDA in Developing Appropriate Drug Dosage and Usage

Rockville, MD – April 2, 2019 – Emmes today announced that it provided the data management support for a study, funded by the National Institutes of Health (NIH) and approved by the Food and Drug Administration (FDA), to safely use Acyclovir to treat infants infected with the Herpes Simplex Virus. Acyclovir, known by the brand name Zovirax, now includes recommended usage and dosage for newborns and infants up to three months of age on its label.

The Best Pharmaceuticals for Children Act (BPCA) mandates that NIH prioritize therapeutic areas in critical need for pediatric labeling, sponsor pediatric clinical trials, and submit the data to the FDA for consideration for labeling changes. The clinical trials are sponsored by the National Institute of Child Health and Human Development (NICHD), with the labeling reviews and approvals administered by the FDA.

In the NIH news release, Dr. Perdita Taylor-Zapata, BPCA program lead at NICHD, stated: “With this label change, healthcare providers have clear guidance on how to use and prescribe this drug for their youngest patients.”

Newborns can become infected with the virus during pregnancy, labor and delivery, or shortly after birth if the mother develops genital herpes near the end of her pregnancy. The Herpes Simplex Virus in newborns can cause death or long-term problems such as blindness and damage to the brain and other organs.

Emmes has served as a data coordinating center for the BPCA contract since August 2009. This entails study design, data management, regulatory support, pharmacovigilance, site monitoring, and statistical analyses.

Dr. Anne Lindblad, president and chief executive officer of Emmes, said, "This is one of our largest contracts and one that our Emmes team is extremely proud to support. Our role as a data coordinating center is a critical step in the process to study drugs and therapies used for infants and children and determine whether drug labeling updates are needed."

The Best Pharmaceuticals for Children Act was enacted in 2002 and subsequently reauthorized by the U.S. Congress in 2007, 2012 and 2017. One of its goals involves conducting clinical trials and research for on- and off-patent drug products meriting further study for children. NICHD activities are aimed at improving pediatric drug therapies through preclinical and clinical testing that lead to drug labeling change.

Most new drugs that have potential applications in pediatric care must be tested in children prior to receiving marketing approval in the U.S. However, the majority of previously approved drug therapies have not been labeled specifically for children and are used off-label without adequate studies in children.

Acyclovir is the first BPCA drug labeling change in 2019, and others are likely to follow.

Lindblad added, "Nine other drugs associated with this BPCA project are in various stages of review at the FDA. Ultimately, what this means is that more infants, young children and teenagers will benefit from careful labeling and appropriate treatment options for a variety of diseases."

About Emmes

We collaborate with our clients to produce valued, trusted scientific research. Our team members at Emmes are passionate about making a difference in the quality of human health, and we have supported more than a thousand studies across a diverse range of diseases since our formation in 1977. Our research is contributing to a healthier world. For more information, visit the Emmes website at www.emmes.com.