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Emmes Leads Clinical Trials to Improve Pediatric Drug Labeling

Study results spur FDA to approve enhanced pediatric labeling

Rockville, MD – February 1, 2021 – Emmes, a global, full-service Clinical Research Organization dedicated to supporting the advancement of public health and biopharmaceutical innovation, today announced significant progress in its role as Data Coordinating Center for studies conducted under the Best Pharmaceuticals for Children Act (BPCA).

Results from the Emmes-managed clinical trials, conducted through the BPCA Clinical Coordinating Center at Pediatric Trials Network, contributed directly to improved drug labeling for a range of products used in treating infants and children. The four newest label changes related to caffeine citrate, used to treat apnea of prematurity, plus three antibiotics: doxycycline, clindamycin, and trimethoprim-sulfamethoxazole (often referred to by its trade name Bactrim™). With the revised labeling for Ampicillin, announced early last year, there were a total of five Emmes-supported label changes during 2020.

According to Ravinder Anand, Ph.D., Emmes' Vice President of Maternal Child Health, "These are the most approvals ever gained in a single year under the BPCA program. We are proud of our role in these accomplishments for our client, the National Institute of Child Health and Human Development (NICHD)."

He added, "The improvements associated with these label changes provided weight base dosing recommendations for clindamycin; information on pediatric pharmacokinetics for doxycycline and Bactrim; and a broader treatment-eligible age range and extended treatment duration when using caffeine to treat premature infants with apnea of prematurity."

Under the NICHD contract, Emmes provides end-to-end clinical study support and management, which includes data management, regulatory support, pharmacovigilance, site monitoring, and statistical analyses for the studies. The company has served as the Data Coordinating Center for the BPCA program since August 2009 and has supported 11 labeling and two other marketing approvals from the U.S. Food and Drug Administration (FDA). These changes have addressed either pharmacokinetics, dosage, safety and/or efficacy information for a variety of pediatric drugs and devices across various pediatric populations and treatment indications.

Emmes' Chief Executive Officer, Dr. Christine Dingivan, said, "These drug labeling approvals reinforce our commitment to excellence in study design, execution and analysis. This is an important public sector program and a valued client. Emmes has a long history of pediatric clinical research, and our team is so proud of our role in improving public health outcomes and safe, effective drug development in children."

About the Research

The BPCA program is funded by the National Institutes of Health through its Eunice Kennedy Shriver National Institute of Child Health and Human Development. This program supports the Pediatric Trials Network, which studies commonly prescribed off-patent drugs whose original development did not include pediatric patients. Study results are intended to amend FDA-approved prescribing information. This project has been funded in whole or in part with Federal funds from the National Institutes of Health under Contract No. HHSN275201700002C.

About Emmes

Founded in 1977, Emmes is a global, full-service Clinical Research Organization dedicated to excellence in supporting the advancement of public health and biopharmaceutical innovation. The company's clients include numerous agencies and institutes of the U.S. federal government and a wide range of biotechnology, pharmaceutical and medical device companies throughout the world. To learn more about how our research is making a positive impact on human health, go to the Emmes website at www.emmes.com.