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Emmes Study Leads to Pediatric Drug Labeling Change for Ampicillin

Work is Associated with the Best Pharmaceuticals for Children Act

Rockville, MD – January 21, 2020 – Emmes today announced that the Food and Drug Administration (FDA) has extended the labeling of ampicillin, a commonly used antibiotic, to include use in infants younger than 28 days in the treatment of serious conditions meningitis and septicemia. FDA's approval was based in part on a National Institute of Child Health and Human Development (NICHD)-funded study, conducted under the Best Pharmaceuticals for Children Act (BPCA).

Emmes provided full-service data management, regulatory support, pharmacovigilance, site monitoring, and statistical analyses for the ampicillin study, and facilitated the study protocol design. Emmes is in the third year of a 10-1/2 year contract supporting pediatric clinical trials aimed at improving the labeling of drugs for pediatric use.

According to Dr. Perdita Taylor-Zapata, BPCA program lead at NICHD, "Children are considered therapeutic orphans due to the lack of dosing, safety and efficacy information for drugs used routinely in this population. Ampicillin is one of the newest drug labeling changes resulting from study data submitted to and approved by the FDA, and it represents another step forward in helping doctors safely prescribe medication to their youngest patients."

Dr. Anne Lindblad, president and chief executive officer of Emmes, said, "Emmes' study design, data management, statistical analysis and other services provide a platform to ultimately ensure that drugs and therapies for children are safe, effective and used in the proper doses."

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.