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## **The Emmes Corporation Wins \$70 Million Contract for Pediatric Research**

*Company will support the goals of the Best Pharmaceuticals for Children Act*

**Rockville, MD – August 2, 2017** – The Emmes Corporation today announced that it was awarded a contract from the National Institutes of Health to support pediatric clinical trials sponsored by the National Institute of Child Health and Human Development (NICHD). Valued at nearly \$70 million, the 10-1/2 year contract will support the NIH’s effort to improve the labeling of drugs for pediatric use.

The company’s role as the data coordinating center involves study design, data management, regulatory support, pharmacovigilance, site monitoring, and statistical analyses.

“This is one of Emmes’ largest contracts,” noted Dr. Anne Lindblad, president and chief executive officer. “More importantly, it reflects the government’s confidence in our ability to support both NIH and the Food and Drug Administration in a broad mandate to protect the nation’s children by ensuring that the medicines are safe, effective and used in the proper doses.”

The [Best Pharmaceuticals for Children Act](#) was enacted in 2002 and subsequently reauthorized by the Food and Drug Administration (FDA) in 2007 and 2012. 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.

“This contract represents an ongoing, successful collaboration between NIH and the FDA,” said Lindblad. “Emmes’ long history in serving both agencies is especially useful, given the broad mission of updating drug labels appropriately to address the needs of children.”

She continued, “What is especially noteworthy about this project is that it does not target one specific disease but a wide population – infants, young children and teenagers. We’re proud to help bring accurate drug labeling to inform physicians, parents and caregivers.”

Emmes held the data coordinating center role in the previous contract with the NICHD, which ran from 2009 to mid-2017.

#### **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](http://www.emmes.com).