

FOR IMMEDIATE RELEASE

Contacts:

Company: Lynn Lewis

301-251-1161

llewis@emmes.com

Media: Karen Vahouny

703-624-2674

kvahouny@gmail.com**Emmes Employees Co-Author Substance Use Article for the New England Journal of Medicine*****Innovative Clinical Trial Design Focused on Treatment for Methamphetamine Use Disorder***

Rockville, MD – February 22, 2021 – Emmes, a global, full-service Clinical Research Organization dedicated to supporting the advancement of public health and biopharmaceutical innovation, today announced its contribution to a [study](#) for the National Institute on Drug Abuse (NIDA) Clinical Trials Network (CTN) and a related [article](#) published in the *New England Journal of Medicine*.

Emmes statisticians Gaurav Sharma, Ph.D., and Aimee Wahle were co-authors of the article, “Bupropion and Naltrexone in Methamphetamine Use Disorder.”

The double-blind, placebo-controlled Phase III clinical trial centered on the use of a combination treatment for adults with moderate or severe methamphetamine use disorder. The study, known as the Accelerated Development of Additive Pharmacotherapy Treatment for Methamphetamine Use Disorder (ADAPT-2), evaluated the efficacy and safety of two medications, injectable naltrexone and oral bupropion. Study participants who received the combination treatment showed a higher response rate than those who received placebo.

“The study findings are cause for optimism,” said Jennifer McCormack, Associate Vice President who leads Emmes’ substance use disorder unit. “The combination of the two medications was shown to be safe and effective, and we now have a strong platform for more research to address the growing methamphetamine crisis in the U.S.”

She continued, “Our clinical trial design team implemented a sequential parallel comparison design, an innovative design that required re-randomization of placebo non-responders in the second stage of the study. We believe the experience of implementing this adaptive design will prove useful in designing future studies of substance use disorder.”

The Emmes project team provided the full-scope support through its Data and Statistics Center and Clinical Coordinating Center contracts with NIDA. The company has collaborated with NIDA on more than 50 clinical trials since 2005.

Paul VanVeldhuisen, Ph.D., President of Emmes Public Sector, noted, “Although opioid use disorder has deservedly received a lot of attention, methamphetamine use disorder is also a serious, growing concern, and it is difficult to treat.”

According to a study published in *JAMA Psychiatry*, methamphetamine overdose deaths surged in an eight-year period in the United States. It is a leading cause of overdose deaths in the Midwest and West.

“The pandemic has intensified concerns about substance use disorders, making treatments even more critical,” Dr. VanVeldhuisen added. “There are currently no medications for treating methamphetamine use disorder that are approved by the U.S. Food and Drug Administration, so the results of the NIDA CTN study are especially encouraging.”

“I’m very proud of the innovative approach that our team implemented to advance critical research addressing this public health crisis,” noted Dr. Christine Dingivan, Chief Executive Officer. “It is a wonderful example of Emmes’ experience and commitment to the important work of clinical trials in the area of substance use disorders.”

About the Research

This project has been funded in whole or in part with Federal funds from the National Institutes of Health under Contracts No. HHSN271201400028C and HHSN271201500065C.

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.