

Neuroscience

Emmes' Neuroscience experience includes a diverse array of clinical research programs across the CNS space including epilepsy, traumatic brain injury, stroke, major depression, substance use, autism, schizophrenia, multiple sclerosis as well as numerous rare neurological diseases.

Emmes provides full-service CRO support for Neuroscience clinical trials for biopharma companies and the public sector where we have served as a long-standing partner to the National Institute of Neurological Disorders and Stroke (NINDS), as well as the National Institute of Mental Health (NIMH).

Examples of Emmes' commitment to mental health include our support for:

- Multi-site randomized controlled trials of psilocybin across various CNS indications, where Emmes partners with leaders in the field of psychedelic drug development in an effort to investigate the potential of this breakthrough therapy.
- The Neonatal Effects of Antiepileptic Drug (NEAD) Study and Maternal Outcomes and Neurodevelopmental Effects of Antiepileptic Drug (MONEAD) Study which seek to understand the effects of antiepileptic drugs on pregnant women and their children.
- The National NeuroAIDS Tissue Consortium (NNTC) whose mission is to collect, store and distribute biospecimens from HIV positive and negative patients to further our understanding of NeuroAIDS disorders.
- The Brain Injury and Mechanisms of Action of Hyperbaric Oxygen for Persistent Post-Concussive Symptoms after Mild Traumatic Brain Injury Study investigating treatment for chronic symptoms in active duty US military service members who had suffered the signature wound of war.
- The NINDS Center for Clinical Research Resources (CCRR), where Emmes serves as a leader in the field of data harmonization supporting the creation of common definitions and metadata, which enable data sharing among researchers involved in studying neurological disorders.

Key Facts:

As the Study Coordinating Center for several clients focused on psychedelic drug development:

- Over 5 years of experience providing full scope support for rigorously conducted multi-center psychedelic trials.
- Support includes CNS trials in depression and substance use space.
- Successfully navigated challenges unique to Schedule I drug studies, e.g., DEA license acquisition, Schedule I IP management and accountability, and determining data collection and analysis solutions to FDA concerns about abuse liability.

Highlights Include:

- 22 years supporting the NEAD and MONEAD studies which have generated over 60 research articles, book chapters, reviews, and abstracts, with additional manuscripts being published on an ongoing basis. NEAD and MONEAD primary research and review articles have been published in journals that include The New England Journal of Medicine, Neurology, JAMA, JAMA Pediatrics, JAMA Neurology, Lancet Neurology, Epilepsia, and Nature Review Neurology.
- Development of user-friendly interactive query tool for NNTC to put information into the hands of investigators and help them understand the rich resources available in the biorepository and study database.
- Significant experience integrating data from disparate sources including clinical data, patient reported outcomes, neurological diagnostic tools (e.g., CT, structural MRI, DTI, fMRI, MR spectroscopy, EEG), wearables, daily seizure and medication diaries, etc.
- 9 years as a NINDS CCRR leader. Emmes has increased the number of the NINDS common data elements from just under 5,000 to over 18,000, with approximately 1,400 template case report forms across 24 neurological disorder areas.

For additional information on our
Neuroscience Experience, please visit
www.emmes.com/neuroscience