

## **The Truth of the Matter Blog Series**

### **The New Psychedelic Era: Evolving Trials to Unlock their Potential for Patients**

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From ancient times, people have made connections between mind-altering substances and healing. In the 1950s and 1960s, research began to demonstrate that psychedelic drugs (psychoactive substances that cause changes in mood, perception, and some cognitive processes) showed promise in treating addiction and mental health disorders. However, they were included as Schedule 1 drugs in the Controlled Substances Act of 1970, dramatically reducing research into their medical value for many years.

As our understanding and research processes have evolved, it's been exciting to see more support and funding for clinical research into the use of psychedelics. To name just a few examples, in 2021, Johns Hopkins University received a multimillion-dollar grant to investigate the use of psilocybin on tobacco addiction. The 2024 National Defense Authorization Act (NDDA) includes funding for psychedelics research involving military service members with post-traumatic stress disorder or traumatic brain injuries. And just this month, the European Union announced PsyPal, the first EU-funded clinical project focused on using psychedelics to assist with mental health treatments.

Recently, I served as a statistician and corporate oversight for a Phase II clinical trial using psilocybin as an intervention for major depressive disorder (MDD) that yielded encouraging results. As the team shared in the paper "Single-Dose Psilocybin Treatment for Major Depressive Disorder: A Randomized Clinical Trial," published in the *Journal of the American Medical Association* in 2023, "Psilocybin treatment was associated with a clinically significant sustained reduction in depressive symptoms and functional disability, without serious adverse events. These findings add to increasing evidence that psilocybin—when administered with psychological support—may hold promise as a novel intervention for MDD."

Results such as these make me optimistic about the potential of psychedelics to improve the human experience and inspire me to help overcome the distinctive challenges that come with this type of research. After all, trials involving psychedelic substances aren't the same as traditional clinical trials. For instance, you don't simply hand someone a pill and send them on their way. It's difficult to maintain blinding – for the patients and the clinicians – when the intervention being tested is a psychedelic substance. Then there's the role psychotherapy should play in conjunction with the substance administered. Special care needs to be taken in designing the trial, ensuring the right separation of roles, and providing site staff with the specific training and understanding needed to execute the study.

From just these few examples, it's clear that trials involving psychedelic substances require specialized expertise, and those interested in this research will want to partner with a CRO that truly understands both the challenges and the solutions.

With 7+ years of experience supporting larger multi-site clinical trials in the psychedelic space, the Emmes Group understands the big picture and the nuances. We want to use our rare and valuable experience to help sponsors unlock exciting new treatments for patients.

We've developed relationships with many of the sites who are at the forefront of this research. We understand their infrastructure, capabilities and working styles and have unique insight into site performance specifically in psychedelic clinical trials. We also know that the number of sites with

Schedule 1 licenses is limited. Developing and maintaining strong relationships with these in-demand sites is vital, and we make these partnerships a priority.

Carefully selecting and clearly defining endpoints is critical to the success of all clinical trials and is absolutely key in unlocking the potential of psychedelic treatments. Through the Emmes Group's experience in psychedelic research as well as our full neuroscience portfolio, which includes work with the National Institute on Drug Abuse (NIDA) and National Institute of Neurological Disorders and Stroke (NINDS), we have an unmatched perspective on endpoint selection. We participate in the generation of consensus-driven recommendations for endpoint selection in neurology and psychiatry applications as part of the National Institutes of Health (NIH) common data element initiative. As a result, we are able to guide sponsors in defining endpoints that are right for their psychedelic clinical trials.

As noted, the patient experience in a psychedelic trial is much different than in a trial testing a more traditional treatment. The Emmes team takes that into account as well as the FDA's guidance series on patient-focused drug development. This guidance places a significant focus on incorporating patient perspective in clinical development programs. We have in-house capabilities to provide full-scope support for qualitative interviews that can be invaluable in psychedelic trials because of the unique and varied experiences people have during their dosing sessions.

If you attended the Multidisciplinary Association for Psychedelic Studies (MAPS) conference in 2023, you may have experienced firsthand enlightening presentations that paired quantitative evidence with representative quotes and videos telling the stories of individual patient stories, both of their disease experience as well as with the psychedelic intervention itself. The combination of those two sources of data was powerful. Emmes can amplify patient voices in psychedelic research.

With our unique experience, capabilities and relationships, we can truly help our research partners develop the data to expand our understanding and unlock the future of psychedelic interventions.

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Additional resources on this topic you may find valuable:

[Identifying and Selecting Sites for Psychedelic Clinical Trials](#)

[Unlocking the complexities of psychedelic clinical trials and FDA's approach to guidance](#)