



## MAPS Completes Enrollment, as Planned, for the Confirmatory Phase 3 Trial of MDMA-Assisted Therapy for PTSD

FOR IMMEDIATE RELEASE: May 9, 2022

- *The second, confirmatory Phase 3 trial of MDMA-assisted therapy for PTSD is now fully enrolled at 13 sites in the United States and Israel*
- *Completion of enrollment on schedule supports targeted submission of the New Drug Application to the FDA in the first half of 2023*
- *Health Equity initiatives to enroll BIPOC and LGBTQIA+ participants improved representation of populations most likely to develop PTSD following exposure to trauma*

The non-profit [Multidisciplinary Association for Psychedelic Studies](http://maps.org/) < <http://maps.org/>> (MAPS) and [MAPS Public Benefit Corporation](http://mapspublicbenefit.com/) < <http://mapspublicbenefit.com/>> (MAPS PBC), a wholly-owned subsidiary of MAPS, announced that a blinded administrative interim analysis has confirmed no changes to the planned sample size are necessary to provide sufficient statistical power to detect efficacy of MDMA-assisted therapy for posttraumatic stress disorder (PTSD) in the second of two Phase 3 trials ([MAPP2](https://maps.org/mdma/ptsd/mapp2/) < <https://maps.org/mdma/ptsd/mapp2/>> ). Per the special protocol agreement negotiated with the U.S. Food and Drug Administration (FDA) for the confirmatory trial, MAPP2 was designed to enroll at least 100 participants in order to confirm the efficacy and further investigate the safety of the treatment.

“ For nearly 20 years, MAPS has sponsored innovative, careful research into the potential of MDMA to treat PTSD. MAPS PBC, supported through the dedication of staff, consultants, participants in the studies, and donors, has organized world-class research into a novel treatment for a devastating condition with too few treatment options. Together, we are eagerly awaiting the possibility that our scientific inquiry may be confirmed in this critically important trial scheduled to be completed in October 2022.

[Amy Emerson < https://mapspublicbenefit.com/staff/amy-emerson/ >](https://mapspublicbenefit.com/staff/amy-emerson/), CEO, MAPS PBC

The [first Phase 3 trial < https://maps.org/mdma/ptsd/mapp1/ >](https://maps.org/mdma/ptsd/mapp1/) of MDMA-assisted therapy for PTSD indicated that it may be a safe and effective treatment for PTSD resulting from any cause, with 88% of participants demonstrating a [clinically significant reduction in PTSD symptoms < https://maps.org/news/media/maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd/ >](https://maps.org/news/media/maps-phase-3-trial-of-mdma-assisted-therapy-for-ptsd-achieves-successful-results-for-patients-with-severe-chronic-ptsd/) two months after the last experimental session with no serious safety signals emerging. If the MAPP2 study results, available after October 2022, are statistically significant for a reduction in PTSD symptoms and meet the FDA standards for safety, MAPS and MAPS PBC are planning to submit a New Drug Application to the FDA in the first half of 2023.

It is estimated that more than 300 million people are living with PTSD worldwide. In the United States, about 12 million people experience PTSD each year. About half of people with PTSD achieve symptom reduction through psychotherapy or pharmaceutical interventions. For many others, PTSD is a chronic condition resulting in serious comorbidities including anxiety, insomnia, hypertension, depression, and substance use disorder.

“ The completion of enrollment brings us one step closer to making this novel treatment available to the many people who were not able to participate and accessible to those who need it most. We are ever grateful for the participants who spent many hours on their healing journeys in this trial and to the therapists, study coordinators, doctors, and MAPS PBC staff who have dedicated their careers to this effort.

[Charlotte Harrison, B.A. < https://mapspublicbenefit.com/staff/charlotte-harrison-b-s/ >](https://mapspublicbenefit.com/staff/charlotte-harrison-b-s/), Associate Director for Pivotal Programs

Among Americans exposed to trauma, [people of color < https://www.ptsd.va.gov/publications/rq\\_docs/V31N4.pdf >](https://www.ptsd.va.gov/publications/rq_docs/V31N4.pdf) and [LGBTQIA+ individuals < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7223966/ >](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7223966/) are more likely to develop PTSD, yet less likely to receive a diagnosis or have reasonable access to treatment. Research demonstrates that [racial and ethnic alignment < https://www.pnas.org/doi/full/10.1073/pnas.1913405117 >](https://www.pnas.org/doi/full/10.1073/pnas.1913405117) among healthcare providers and their patients can improve survival, safety, and trust for patients. However, marginalized populations are [historically underrepresented < https://akjournals.com/view/journals/2054/4/1/article-p4.xml >](https://akjournals.com/view/journals/2054/4/1/article-p4.xml) in clinical research, including in MAPS-sponsored trials. Through equity initiatives in therapist training and participant recruitment, participants in MAPP2 are more representative of the population of people living with PTSD.

The double-blinded clinical trial randomized participants to a group receiving MDMA-assisted therapy or a control group receiving an identical therapy protocol with inactive placebo. Both are delivered by practitioners who have received extensive training in MAPS PBC's [MDMA Therapy Training Program < https://mapspublicbenefit.com/training >](https://mapspublicbenefit.com/training). The investigational treatment, which has been granted [Breakthrough Therapy < https://maps.org/news/media/press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials/ >](https://maps.org/news/media/press-release-fda-grants-breakthrough-therapy-designation-for-mdma-assisted-psychotherapy-for-ptsd-agrees-on-special-protocol-assessment-for-phase-3-trials/) designation by the FDA, consists of eligibility screening, three 90-minute preparatory sessions, three eight-hour MDMA-assisted therapy sessions, and at least nine 90-minute

integration sessions, with additional integration sessions provided as needed through the study completion visit.

For more information about MAPP2 and other ongoing MAPS-sponsored trials, please visit [mdmaptsd.org](http://mdmaptsd.org) < <http://mdmaptsd.org>> .

## NOTE

The safety and efficacy of MDMA-assisted therapy is currently under investigation. It has not yet been approved by the FDA or other regulatory authorities, does not work for everyone, and carries risks even in therapeutic settings. These statements are no guarantee of future regulatory approval or availability of MDMA-assisted therapy. These statements necessarily involve known and unknown risks and uncertainties, which may cause actual outcomes to differ materially from our projections.

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## MEDIA CONTACT

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## ABOUT [MAPS](http://maps.org) < <http://maps.org>>

Founded in 1986, MAPS is a 501(c)(3) non-profit research and educational organization that develops medical, legal, and cultural contexts for people to benefit from the careful uses of psychedelics and marijuana. MAPS is sponsoring the most advanced psychedelic therapy research in the world: Phase 3 clinical trials of MDMA-assisted therapy for PTSD. Since MAPS was founded, philanthropic donors and grantors have given more than \$130 million for psychedelic and marijuana research and education. MAPS has earned both the [Guidestar Platinum Seal of Transparency](https://www.guidestar.org/profile/59-2751953) < <https://www.guidestar.org/profile/59-2751953>> and a [4-Star Rating from Charity Navigator](https://www.charitynavigator.org/ein/592751953) < <https://www.charitynavigator.org/ein/592751953>> .

## ABOUT [MAPS PUBLIC BENEFIT CORPORATION](http://mapspublicbenefit.com) < <http://mapspublicbenefit.com>> (MAPS PBC)

MAPS Public Benefit Corporation (MAPS PBC) catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics while prioritizing public benefit above profit. Founded in 2014, MAPS PBC is a wholly-owned subsidiary of the Multidisciplinary Association for Psychedelic Studies (MAPS), a 501(c)(3) non-profit organization. It is the parent company of MAPS EU, formed to organize and administer clinical trials of MDMA-assisted therapy for PTSD in the United Kingdom and European Union.

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