

## Developing MDMA into a Prescription Medicine

MAPS' top priority is developing MDMA-assisted psychotherapy into a legal, Food and Drug Administration (FDA) and European Medicines Agency (EMA)-approved treatment for PTSD caused by sexual assault, war, violent crime, or any other trauma. Our Phase 2 studies have shown that MDMA in conjunction with psychotherapy can help people overcome chronic, treatment-resistant PTSD. MDMA (3,4-methylenedioxymethamphetamine) is a semi-synthetic compound patented by Merck in 1914 and now in the public domain. MDMA decreases activity in the left amygdala (associated with fear and traumatic memories); increases activity in the frontal cortex; and promotes the release of oxytocin and prolactin, hormones associated with love and bonding. MDMA can decrease fear and defensiveness while increasing trust and empathy. In MDMA-assisted psychotherapy, MDMA is administered up to three times, in the context of a several month process of non-drug psychotherapy, unlike most medications for mental illnesses which are often taken daily for years.

## Phase 3 Trials: MDMA-Assisted Psychotherapy for PTSD

Our FDA-regulated Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD are taking place at approximately 15 locations across the United States, Canada, and Israel. Preparations for Phase 3 trials in Europe are also underway through Phase 2 studies and negotiations with EMA. The Phase 3 clinical trials are assessing the efficacy and safety of MDMA-assisted psychotherapy in adult participants with severe PTSD. Over a 12-week treatment period, participants receive 12 non-drug preparatory and integration sessions, lasting 90 minutes each, along with three day-long psychotherapy sessions assisted by either MDMA or placebo. The primary endpoint is the Clinician Administered PTSD Scale (CAPS-5), as assessed by a blinded pool of independent raters. The trials are the final phase of research required by the FDA to gather adequate efficacy and safety data that could potentially lead to approval of MDMA as a legal prescription treatment for PTSD. If approved, MDMA will be required to be used in conjunction with psychotherapy under direct observation in an outpatient setting.

## Completed Phase 2 Trials: MDMA-Assisted Psychotherapy for PTSD

On May 7, 2019, the overall results of six Phase 2 clinical trials of MDMA-assisted psychotherapy for the treatment of posttraumatic stress disorder (PTSD) were published in the peer-reviewed journal *Psychopharmacology*. The publication is the most comprehensive analysis of the safety and efficacy of MDMA-assisted psychotherapy for treatment of PTSD. Sponsored by MAPS, the double-blind, controlled Phase 2 trials in 103 subjects found that 54% of participants in the active treatment group (75–125 mg MDMA) did not qualify for a diagnosis of PTSD, compared to 23% in the control group (0–40 mg MDMA). In the published analysis, the course of double-blind treatment included two eight-hour MDMA-assisted psychotherapy sessions spaced three to five weeks apart, combined with weekly non-drug psychotherapy sessions. The trials were conducted by independent investigators in Charleston, South Carolina (two trials); Boulder, Colorado; Vancouver, British Columbia; Solothurn, Switzerland; and Beer Yaakov, Israel. Trial participants included men and women with chronic PTSD from a variety of causes.

## Breakthrough Therapy Designation: MDMA-Assisted Psychotherapy for PTSD

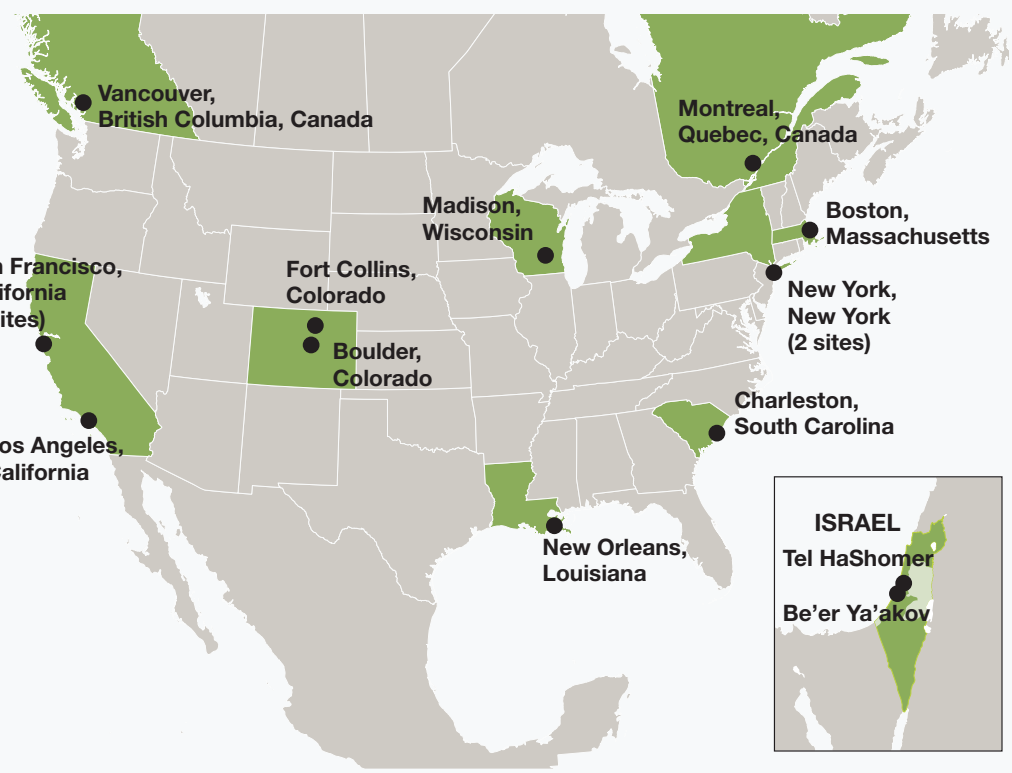
On August 16, 2017, the FDA granted Breakthrough Therapy Designation to MDMA for the treatment of PTSD. The FDA grants this designation for treatments that (1) are intended alone or in combination with one or more other drugs to treat a serious or life-threatening disease or condition; and (2) preliminary clinical evidence indicates substantial improvement over existing therapies. A Breakthrough Therapy Designation signals that this treatment may have a meaningful advantage and greater compliance over available medications for PTSD.

## Participate in Research

MAPS sponsors clinical trials around the world that offer eligible volunteers the opportunity to participate in our research studies. Our studies have strict enrollment criteria based on the goal of the study and the condition the study is investigating. To learn more, visit [maps.org/participate](https://maps.org/participate).

## Phase 3 Study Locations

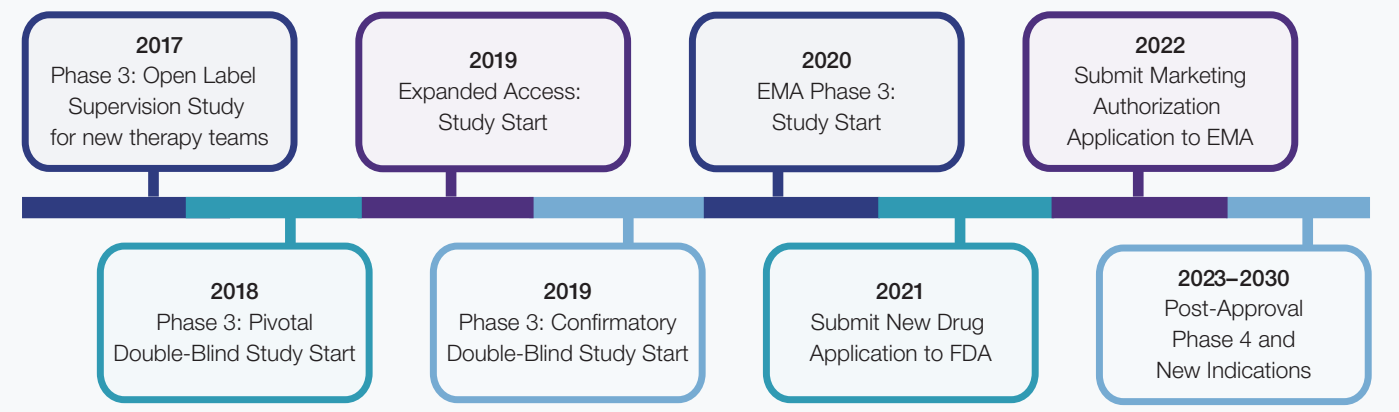
Phase 3 clinical trials of MDMA-Assisted Psychotherapy for PTSD began in late 2018. The study aims to enroll 200–300 participants across approximately 15 sites in the U.S., Canada and Israel. Results will be submitted to the FDA in 2021 with approval expected in 2022.



## Phase 3 Study Design



## Timeline for Regulatory Approval



## MDMA-Assisted Therapy for Social Anxiety in Autistic Adults

MAPS' randomized, double-blind, placebo-controlled Phase 2 study assessed the safety and feasibility of MDMA-assisted psychotherapy to treat social anxiety in 12 MDMA-naïve autistic adults. This study obtained pilot data based on two experimental MDMA-assisted psychotherapy sessions and associated non-drug preparatory and integrative sessions, in comparison to an inactive placebo control group with the same non-drug preparatory and integrative sessions. The trial results were published in *Psychopharmacology* in 2018. There are currently no FDA-approved pharmacological treatments for autistic adults with social anxiety, and conventional anti-anxiety medications lack clinical effectiveness in this population.

## MDMA-Assisted Psychotherapy for Anxiety Associated with Life-Threatening Illness

MAPS' randomized, double-blind, placebo-controlled Phase 2 study gathered preliminary data about the safety and efficacy of MDMA-assisted psychotherapy for anxiety in 18 participants diagnosed with a life-threatening illness. Outcomes included treatment-related changes in anxiety, depression, sleep quality, quality of life, self-reported and observer-reported changes in attitudes, attitudes toward death and the prospect of death, and changes in self-compassion and self-reported mindfulness.

## Medical Cannabis for Symptoms of Posttraumatic Stress Disorder

MAPS is the leading organization working to demonstrate the safety and efficacy of whole-plant cannabis as a prescription medicine. Our study was the first controlled study ever conducted to explore whether smoking cannabis could help reduce PTSD symptoms in 76 U.S. veterans with chronic, treatment-resistant PTSD. On February 8, 2019, we officially completed this first-ever clinical trial of smoked cannabis as a treatment for PTSD symptoms, with all 76 veterans enrolled and treated. The data from the study are now being analyzed and prepared for publication later this year in a peer-reviewed biomedical journal.

## LSD-Assisted Psychotherapy

MAPS has completed the first double-blind, placebo-controlled study of the therapeutic use of LSD in humans since the early 1970s. LSD (lysergic acid diethylamide) is a semi-synthetic compound first developed in 1938 by Dr. Albert Hofmann at the Sandoz pharmaceutical company in Basel, Switzerland. After Dr. Hofmann first discovered its effects in 1943, LSD quickly became recognized for its possible therapeutic effects. Our completed Phase 2 pilot study in 12 subjects found positive trends in the reduction of anxiety following two LSD-assisted psychotherapy sessions. The study results published in the *Journal of Nervous and Mental Disease* in 2014 indicate that LSD-assisted psychotherapy can be safely administered in these subjects, and justify further research.

## Ibogaine Therapy for Drug Addiction

On May 25 and April 12, 2017, the promising results of MAPS-sponsored observational studies of treating opioid dependence with ibogaine-assisted therapy were published in the peer-reviewed *American Journal of Drug and Alcohol Abuse*. Sponsored by MAPS in Mexico and New Zealand, both studies show that ibogaine could be a potential treatment for opioid dependence and rigorously controlled studies are warranted. The investigators conclude that ibogaine demonstrates the potential for substantive treatment effect that can enable opioid detoxification in treatment-resistant opioid-dependent participants through a novel pharmacological mechanism of action. Ibogaine is a traditionally-used psychoactive compound naturally occurring in the West African shrub iboga.

## Ayahuasca-Assisted Treatment for Addiction

MAPS funded the first North American observational study of the safety and long-term effectiveness of ayahuasca treatment for addiction and dependence. The paper describing the results of the study was published in June 2013 in *Current Drug Abuse Reviews*. Ayahuasca is a psychoactive brew most commonly derived from *Banisteriopsis caapi*, a vine containing monoamine oxidase inhibitors (MAOIs), and the leaves of *Psychotria viridis* or other plants containing N,N-dimethyltryptamine (DMT).

## About MAPS

### MAPS furthers its mission by:

- Developing psychedelics and cannabis into prescription medicines
- Training therapists and establishing a network of treatment centers
- Supporting scientific research into spirituality, creativity, and neuroscience
- Educating the public honestly about the risks and benefits of psychedelics and cannabis.



## About MAPS Public Benefit Corporation (MAPS PBC)

All MAPS-sponsored research is conducted by the MAPS Public Benefit Corporation (MAPS PBC). MAPS PBC catalyzes healing and well-being through psychedelic drug development, therapist training programs, and sales of prescription psychedelics 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) nonprofit.

## Join the Conversation

Learn more about our research and education programs at [maps.org](https://maps.org).

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Founded in 1986, the Multidisciplinary Association for Psychedelic Studies (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.

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