Pathway to Approval

We Need Your Support for Phase 3 Clinical Trials of MDMA-Assisted Psychotherapy for Posttraumatic Stress Disorder

maps.org
Mission
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.

Vision
MAPS envisions a world where psychedelics and marijuana are safely and legally available for beneficial uses, and where research is governed by rigorous scientific evaluation of their risks and benefits.

Values
• Transparency
• Passion and Perseverance
• Intelligent Risk
• Trust and Accountability

Making MDMA a Medicine
On November 29, 2016, the U.S. Food and Drug Administration (FDA) agreed for the first time to Phase 3 research to develop a psychedelic drug into a prescription medicine as an adjunct to psychotherapy.

Creating Legal Contexts
MAPS’ primary strategy is to sponsor drug development research regulated by the FDA and European Medicines Agency (EMA) for MDMA-assisted psychotherapy for people suffering from chronic PTSD.

Clinical Research Milestones
At MAPS’ November 29, 2016, End of Phase 2 meeting, the FDA reviewed data from MAPS’ international series of pilot studies investigating MDMA-assisted psychotherapy for PTSD. Satisfied, the FDA agreed to allow MAPS to start planning our pivotal multi-site Phase 3 studies required to prove safety and efficacy prior to applying for prescription approval. On January 13, 2017, MAPS submitted its Phase 3 protocol to the FDA for review under the Special Protocol Assessment (SPA) process, receiving FDA comments on March 9. On April 3, 2017, MAPS submitted its reply to the FDA. We anticipate completing the SPA process by Summer 2017.

Completing Phase 3 clinical trials of MDMA-assisted psychotherapy will transform the fields of psychiatry and psychotherapy.

Help us make MDMA-assisted psychotherapy an FDA-approved prescription treatment for PTSD.
I am a combat veteran who served for 12 years in both the Marines and the U.S. Army. I was deployed to Iraq in 2005, and came home in late 2006 with a traumatic brain injury (TBI) and severe posttraumatic stress disorder (PTSD).

In the early hours of Christmas morning after returning home in 2006, I sought help at both a church and an Army hospital but was turned away by both. I drank a bottle of vodka, loaded a Beretta M9, put it to my temple, and pulled the trigger. The gun misfired.

Every day, more than 20 veterans have a similar experience, and are not as lucky as I was; instead they are buried under the flag of the country they loved and died defending.

I was fortunate enough to participate in one of MAPS’ recently completed Phase 2 studies. MDMA-assisted psychotherapy must be added to the arsenal of treatments available to veterans, first responders, and the many others with PTSD.

I do not use the term “cure” lightly, as real cures are rare in modern medicine, but due to this treatment, I went from being severely suicidal to working as the National Veterans Director for Rand Paul’s presidential campaign.

The most commonly used Veterans Affairs-approved treatments are Cognitive Processing Therapy (CPT) and Prolonged Exposure Therapy (PE). While these treatments do improve symptoms for about 70% of the veterans who received them, two-thirds still meet the clinical definition of PTSD—and of course, 30% don’t improve at all.

Anxiety disorders have an annual domestic cost of $42.3 billion, and PTSD is the most costly. PTSD is a leading cause of veteran homelessness, substance abuse, and unemployment, and 24.4 million Americans will suffer from PTSD during their lifetime. Over 500,000 veterans who served in Iraq or Afghanistan suffer from PTSD.

By enabling veterans to get off disability and return to work, this treatment could reduce the need for VA services, improve wait times, and reduce reliance on Social Security. Such improvements in a single veteran’s health could produce over $1 billion in taxpayer savings over 20 years.

I am fortunate to have been one of the few who has received this life-changing treatment. While I’m always appreciative to the many people who have thanked me for my service, I would rather they donate to MAPS and show their gratitude by helping save the lives of my brothers and sisters.

Your donation to MAPS—large or small—will help ensure that a young child will not be presented a folded flag on behalf of a “grateful nation” in recognition of a parent who took their own life. This treatment has made it possible for me to watch my son grow up, fall in love, have his heart broken, go to prom, get married, and hopefully, one day, hold my grandchildren.

Someday, when my son is old and gray, he will be presented with my flag—but thanks to MDMA-assisted psychotherapy, that day is not today.

Very Respectfully,

Jonathan M Lubecky
Sergeant (Retired)
US Army
PTSD is a worldwide public health problem.

PTSD is a serious debilitating disorder that can arise after a traumatic experience. Approximately 7% of the U.S. population, and up to 17% of veterans will have PTSD sometime in their life. As of June 2016, more than 868,000 veterans with PTSD received disability compensation from the Department of Veterans Affairs, with an estimated cost of more than $17 billion per year.

“One of the greatest challenges for people with PTSD is their distorted sense of self. In therapy, MDMA can enable a person to experience the accepting, compassionate, and worthy self within them.”
—Marcela Ot’alora, MA, LPC, Clinical Investigator

Living with PTSD

People who suffer from PTSD relive their traumatic experiences through nightmares and flashbacks, have difficulty sleeping, and feel detached or estranged. Symptoms can be severe and long lasting. PTSD negatively impacts a person’s daily life, and can result in:

• Diminished cognitive and psychosocial functioning
• Fractured relationships
• An inability to maintain employment
• Substance abuse
• High-cost healthcare
• Depression
• Suicide

Existing Treatments

Existing FDA-approved medications are usually taken daily in order to alleviate PTSD symptoms. These treatment regimens work for many patients but roughly 33–50% of PTSD patients, especially those with severe PTSD, do not respond adequately to currently available medicines or evidence-based psychotherapies.
MDMA is a powerful tool for patient and clinician.

MDMA (3,4-methylenedioxymethamphetamine) is a ring-substituted phenylisopropylamine derivative invented by the Merck pharmaceutical company in 1912. MDMA is a monoamine releaser and re-uptake inhibitor, and indirectly causes the release of hormones—such as oxytocin and prolactin—associated with trust and bonding. These combined effects reduce defenses and fear of emotional injury, enhance communication and introspection, and increase empathy and compassion.

Effects of MDMA

The subjective effects of MDMA create a productive psychological state that may enhance the therapeutic process. The acute effects of MDMA may include:

- Increased feelings of empathy and compassion
- Enhanced abilities of communication and introspection
- Reduced feelings of fear
- Increased feelings of well-being
- Increased sociability and extroversion
- Increased interpersonal trust
- Alert state of consciousness

Healing PTSD

Data from MAPS’ international series of Phase 2 pilot studies of MDMA-assisted psychotherapy provide strong evidence that chronic PTSD, regardless of its cause, is treatable with two to three sessions of MDMA-assisted psychotherapy and associated non-drug preparatory and integrative psychotherapy.

MDMA-assisted psychotherapy is a fundamentally different mode of treatment from the daily, chronic administration of SSRIIs or other psychiatric medications. With many advantages over existing treatments, namely efficacy, tolerability, and duration of effects, MDMA-assisted psychotherapy has the potential to greatly impact the lives of millions who suffer from PTSD worldwide.
Phase 2 Clinical Research

In our MDMA-assisted psychotherapy for PTSD studies, MDMA is only administered a few times.

MAPS’ Phase 2 research began in 2001 and includes 107 subjects. These data suggest that MDMA-assisted psychotherapy is safe and effective in treating PTSD and the benefits are durable over time.

MDMA Therapy Training Program

In preparation for Phase 3, MAPS began its MDMA/PTSD Therapy Training Program, which is in the process of training about 120 therapists to work effectively and safely with this novel treatment method.

The five-part training program is led by MAPS-sponsored researchers Michael Mithoefer, M.D., Annie Mithoefer, B.S.N., and Marcela Ot’alora, M.A., L.P.C. The program is a prerequisite for anyone working on a therapy team in a MAPS-sponsored Phase 3 trial. Training began in 2015 and will continue through Phase 3 to prepare for the start of an Expanded Access Program, a Phase 3 study for the European Medicines Agency, and post-approval Licensure.

Five-Part Training

- **Part A**: 14 hour online course.
- **Part B**: Week-long in person group training.
- **Part C**: External workshop and report in a supplementary discipline (Holotropic Breathwork, Somatic Experiencing, Psychedelic Science Workshop, etc).
- **Part D**: Week-long experiential training. Required for Phase 3 therapy teams.
- **Part E**: Evaluation and supervision. Final selection of Phase 3 Therapy Teams. For novice MDMA therapy team members, the first subject will be open-label with video supervision. The data will be used for the analysis of safety but won’t count towards efficacy.
Phase 3 Study Design

For each participant, the study will consist of:

- **Screening Period**: phone screen, informed consent, eligibility assessment, and enrollment of eligible participants

- **Preparatory Period with Enrollment Confirmation**: medication tapering, Preparatory Sessions and Baseline assessments leading to Enrollment Confirmation

- **Treatment Period**: three monthly Experimental Sessions and associated Integrative Sessions over ~12 weeks

- **Follow-up Period and Study Termination**: Four weeks with no study visits followed by Study Termination visit

- **Invitation to participate in Long-term Follow-up (LTFU) extension study**: 12 months after last Experimental Session.

Once the study blind is broken and participants know which treatment they received, all participants in the placebo group will be offered the opportunity to enroll at no cost in an open-label safety extension study to receive the exact same treatment of MDMA-assisted psychotherapy as in the initial study. Data will be included in MAPS’ overall safety database.

“If the results of our first two Phase 3 studies are statistically significant and no new safety concerns are identified, they would be the only Phase 3 studies needed for FDA approval.”
—Amy Emerson, Director of Clinical Research
Timeline for Developing MDMA into a Prescription Medicine for PTSD

Phase 3 Clinical Trials

### Trial 1
- **Spring 2018**
- U.S., Canada, and Israel
- **2016**
  - November
  - End of Phase 2 FDA Meeting Negotiations to begin Phase 3

### Trial 2
- **Spring 2019**
- U.S., Canada, and Israel
- **2017**
  - January–August
  - Special Protocol Assessment and Breakthrough Therapy

### Trial 3
- **mid-2019**
- Europe and the United Kingdom
- **2017**
  - Summer
  - Negotiations with European Medicines Agency (EMA)

On November 29, 2016, we met with the U.S. Food and Drug Administration (FDA) to plan our upcoming Phase 3 clinical trials of MDMA-assisted psychotherapy for posttraumatic stress disorder (PTSD). The outcome was as encouraging as we’d hoped: the FDA is ready for MAPS to move forward with the final stages of research for a New Drug Application (NDA). We plan to sponsor two Phase 3 studies at 14 sites in North America and Israel.

We are currently planning and designing our Phase 3 program with consistent feedback from the FDA. We are progressing through the Special Protocol Assessment (SPA) process, a rigorous and lengthy review of the Phase 3 trial design that will provide greater confidence that the Phase 3 data will be accepted at the time of the NDA. The first round of SPA comments have been received and key design elements of the Phase 3 protocol have been accepted. The FDA has encouraged MAPS to apply for Breakthrough Therapy Designation, which, if approved, could expedite the clinical development of MDMA-assisted psychotherapy for PTSD.

In preparation for eventual marketing of MDMA-assisted psychotherapy for PTSD, we’ll need to ensure that European regulatory requirements are met. These negotiations will begin in Summer 2017 and continue until we obtain approvals for Phase 3 clinical trials in the EU, anticipated to start in mid-2019. Depending on funding and on negotiations about study design and whether U.S. data would be accepted by EMA, MAPS’ third Phase 3 study could begin in mid-2019 primarily in Europe and the United Kingdom.

Thirty participants will be enrolled in our open label study for supervision of MDMA-assisted psychotherapy for severe PTSD beginning in the fall of 2017. Open label means that all participants will receive MDMA, not placebo. This study will contribute to overall safety data and will further calibrate the therapeutic approach of the therapy pairs across the 14 sites that will conduct the double-blind placebo-controlled Phase 3 study.
Between 100 and 150 participants will be enrolled in our double-blind placebo controlled Phase 3 study (MAPP1) of MDMA-assisted psychotherapy for severe PTSD beginning in the spring of 2018. We expect to conduct an interim analysis of our data in the winter of 2018, and complete the study in the spring of 2019. Participants who receive placebo will be invited to participate in our open label crossover study (Spring 2019).

Our application for Expanded Access will be submitted to the FDA in Fall 2018. The program starts in Summer 2019. FDA regulations enable manufacturers of investigational drugs to provide patients access to the drug under certain situations if they cannot participate in a clinical trial, but have a serious disease or condition that may benefit from treatment with the drug. The primary intent is to provide treatment, rather than to collect data about the study drug.

The second Phase 3 study will serve as the confirmatory study for the first Phase 3. Between 100 and 150 participants will be enrolled in our second double-blind placebo controlled Phase 3 study (MAPP2) of MDMA-assisted psychotherapy for severe PTSD beginning in the spring of 2019, with interim analysis of our data occurring in the fall of 2019. We expect the study to be complete in the winter of 2019, and as in our previous studies, participants who receive placebo will be invited to participate in our open label crossover study. We anticipate completing collection of all Phase 3 data in January of 2020.

A pre-NDA meeting with FDA will be requested in Winter 2020. Phase 3 data will be submitted on an ongoing basis in order to expedite FDA review. Ongoing meetings with the FDA are expected as part of the Investigational New Drug (IND) process.

100 or more subjects in each study with treatment-resistant PTSD from any cause in any population (including veterans, sexual assault victims, etc)
Financials
MDMA-Assisted Psychotherapy for PTSD Phase 3 Research Projects

Phase 3 costs are determined primarily by the number of subjects needed for statistically significant results. The larger the treatment effect (effect size), the fewer subjects needed. How many subjects are needed will be unknown until MAPS completes interim analyses of Phase 3 trials, after 60% of the subjects have completed primary outcome measures. Negotiations with the European Medicines Agency (EMA) about their requirements for Phase 3 data will start after FDA negotiations are completed in Summer 2017.

MAPS’ fundraising strategy is to raise all the funds for Scenario 2—roughly $25 million—of which we already have $10 million. With these funds, together with medium to large effect sizes, MAPS will have an excellent chance to obtain FDA and EMA approval. With medium to small effect sizes, MAPS expects to obtain FDA approval at least. Either way, all these funds will be used for Phase 3 MDMA/PTSD trials. Once effect sizes are known, additional funding needs for EMA approval, if any, will be known.

Scenario A: 200 subjects / medium or large effect size
FDA approval likely based on Phase 2 results

Scenario B: 300 subjects
- Option 1: Medium or large effect size
  200 subjects for FDA approval
  100 subjects for EMA approval
  (EMA accepting data from first 200)
- Option 2: Medium or less effect size
  300 subjects for FDA approval
  150 subjects x two studies

Scenario C: 450 subjects / medium or less effect size
150 subjects x two studies for FDA approval
additional study of 150 subjects for EMA approval
(EMA accepting data from first 300)

Projected Costs of Phase 3 MDMA for PTSD Research

- Scenario A: $20,500,000
- Scenario B: $25,000,000
- Scenario C: $35,500,000
**Financials**

**MDMA-Assisted Psychotherapy for PTSD Phase 3 Research Projects**

**SCENARIO A:** Two successful Phase 3 Trials for FDA (100 subjects each, effect size medium or large)

**MDMA/PTSD PHASE III COST PROJECTIONS**

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**Financials**

MDMA-Assisted Psychotherapy for PTSD Phase 3 Research Projects

**SCENARIO B:** Two successful Phase 3 Trials For FDA (150 subjects each, effect size medium or less)

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MDMA-Assisted Psychotherapy for PTSD Phase 3 Research Projects

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<tr>
<td>Phase III Trial 3 (N=150, EMA)</td>
<td>-</td>
<td>209,800</td>
<td>5,147,033</td>
<td>4,076,878</td>
</tr>
<tr>
<td>NDA Process</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>354,060</td>
</tr>
<tr>
<td>Overhead (10% Allocation for Projected)</td>
<td>446,588</td>
<td>837,495</td>
<td>1,278,796</td>
<td>$459,020</td>
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</table>

**Total Phase III MDMA/PTSD Research**

$5,416,171 $9,736,297 $14,611,564 $5,615,820

**Total Phase III Projected Costs**

$35,379,851 over next four years
A Transformative Commitment from Dr. Bronner’s

Along with many thousands of people, it’s been our honor and pleasure to support MAPS’ strategy to fund FDA-approved clinical research on the safety and effectiveness of psychedelic medicine for diverse conditions, and to change the political climate that makes this type of research so difficult to conduct. Dr. Bronner’s, family-owned maker of the top-selling natural brand of soap in North America, has announced it will donate $1 million per year over the next five years to MAPS.

“There is tremendous suffering and pain that the responsible integration of MDMA for treatment-resistant PTSD will alleviate and heal,” says David Bronner, Cosmic Engagement Officer (CEO) of Dr. Bronner’s. “To help inspire our allies to close the funding gap, my family has pledged $1 million a year for five years—$5 million total—by far our largest gift to an NGO partner to date. In part, we were inspired by the incredible example of Ashawna Hailey, former MAPS Board member, who gave MAPS $5.5 million when she died in 2011.”

Dr. Bronner’s gift will be reserved for Phase 3 studies, bringing MAPS significantly closer to raising the $25 to $33 million needed to develop MDMA into an FDA-approved prescription treatment.

We face enormous challenges globally, and psychedelics—used responsibly can help us solve them.

“MAPS’ larger goal is to see psychedelic medicine responsibly integrated into American and global culture, readily available to those who need it most, while helping the rest of us open our hearts and minds to each other and to the miraculous living world we live within. I hope you are as inspired as we are to help them do it.”

—David Bronner, CEO of Dr. Bronner’s, Member of MAPS Board of Directors
Support our Work

Together, we can make MDMA-assisted psychotherapy into a prescription treatment for PTSD.

Research evaluating MDMA-assisted psychotherapy shows promising results for reducing or eliminating symptoms of PTSD. You can help make MDMA a legal medicine and heal people suffering from trauma by making a gift to MAPS to fund Phase 3 clinical trials of MDMA-assisted psychotherapy for PTSD.

Post-approval, prescription MDMA would be sold by MAPS’ wholly owned subsidiary, the MAPS Public Benefit Corporation (MPBC). All profits would support MAPS’ mission, reducing the need for subsequent donations and creating an ongoing revenue stream.

Host a Global Psychedelic Dinner

Join over 850 supporters across 16 countries and host a Global Psychedelic Dinner. Gather your community, start a conversation, and raise funds to make MDMA a legal medicine. Visit psychedelicdinners.org.

Planned Giving

Many supporters have arranged for a future gift by including MAPS in their will or trust. Consider including MAPS in your estate planning.

Funding Priorities and Needs

Our top funding priority is developing MDMA-assisted psychotherapy for PTSD into an FDA-approved prescription treatment by 2021. We estimate that up to $25 million is needed to complete Phase 3 studies and obtain FDA approval. This $25 million might also be sufficient for European Medicines Agency (EMA) approval or up to an additional $10 million might be required (see pages 8–11 for more details). MAPS currently has $10 million in hand or pledged for Phase 3, but the remaining gap will require additional funding sources.

Make an Impact

With your help, we can make MDMA a legal prescription medicine within our lifetimes. Since our founding, every dollar in support of our research has come from visionary donors committed to our mission.
“I was diagnosed with acute-complex PTSD. From my first session, I immediately had an obvious reduction in symptoms. For 20 years I wanted to be free, and I didn’t get any real healing until MDMA-assisted psychotherapy.”

—Rachel Hope

“It has now been 2½ years since I completed my participation. I found MDMA-assisted psychotherapy to be a very useful treatment, and advocate that it be made available to all others with severe PTSD.”

—Nigel McCourry, U.S. Marine veteran

“For the first time, I was able to look at everything I had been running away from my whole life. I feel like the luckiest person in the world because I’ve been given something very few people have: a second chance to create the life that I want.”

—Hania Withem

“I could dig in and connect and mend those broken pieces of me, the smaller terrified little me, and nurture and coddle it.”

—Jessi

“MDMA-assisted psychotherapy taught me on a deep level that ignoring a difficult memory is self-destructive, and it is better to deal with it and learn from it.”

—Tony Macie, U.S. Army veteran

“The combination of the psychedelic and the therapist was such a healing thing for me because I could go places I couldn’t go before. I can’t tell you how valuable that was—how valuable that is.”

—Elizabeth Matthews

“Before my treatment, PTSD was an island on which I was stranded. I now attend weddings, birthdays, church, and even go to the grocery store without panic, finally feeling connected to my life and family again.”

—Ed Thompson, former firefighter

“After only three sessions, I no longer qualified for a diagnosis of PTSD. Now I am able to lead a happy and productive life again. I can enjoy my beautiful relationship with the love of my life and my friends and family.”

—CJ Hardin, U.S. Army veteran