



MAPS and the Psychedelic Science Funders Collaborative (PSFC) have launched a \$30 million Capstone Campaign

Through tax-deductible donations, the Capstone Campaign will support the completion of the Phase 3 clinical trials required to support a New Drug Application (NDA) to the US Food and Drug Administration (FDA). Additionally, the funds raised support corresponding regulatory approvals from the Israeli Ministry of Health and Health Canada, along with the necessary initiatives to provide patient access including therapist training, an Expanded Access program, and other commercialization activities.

MAPS and PSFC have already secured \$10 million in multi-year pledges towards the Capstone Campaign, from the MAPS Board of Directors, PSFC members, and key allies. On June 12, we announced a \$10 million challenge grant. The grant was organized by Tim Ferriss and PSFC. To unlock the challenge funds, we must raise \$10 million in 90 days (by September 10). Learn more at maps.org/capstone.

In the wake of COVID-19, the world is collectively experiencing a traumatic event. While every human in the world is potentially at risk, populations that are particularly affected by the pandemic are more likely to develop acute and chronic symptoms of Posttraumatic Stress Disorder (PTSD), a disabling and potentially life-threatening mental health condition.

A safe and effective treatment for PTSD is needed now, more than ever

The current first-line treatment for PTSD is trauma-focused therapy. This therapeutic approach can be effective in symptom reduction and management for many people with PTSD. However, there is still a significant portion of patients who are treatment-resistant, and the therapies often take years for symptoms reduction to reach remission levels. A comparison between MDMA-assisted psychotherapy and currently approved drugs (Zoloft + Paxil) demonstrated that MDMA-assisted psychotherapy for PTSD, with its integrated approach which blends pharmacology and psychotherapy, constitutes a substantial improvement over existing pharmacotherapies in terms of safety and effectiveness. ([Feduccia, 2019](#))





Breakthrough Therapy, meaning it is among the most promising drugs being developed

The treatment design involves 3 day-long administrations of MDMA-assisted psychotherapy scheduled 3-5 weeks apart in conjunction with twelve weekly 90-minute non-drug psychotherapy sessions: three preparatory sessions before the first, and three integrative sessions after each MDMA-assisted session.

Due to its unique pharmacological profile, MDMA is a powerful adjunct to psychotherapy which assists individuals in processing traumatic experiences in a deep and profound manner leading to the alleviation of suffering. The premise of this treatment approach is that the therapeutic outcome is the result of an interaction between the effects of the medicine, the therapeutic setting, and the mindsets of the participant and the therapists. Research indicates that MDMA may catalyze therapeutic processing by allowing participants to stay emotionally engaged while revisiting traumatic experiences without being overwhelmed by anxiety or other painful emotions.

MAPS-sponsored Phase 2 clinical trials in 105 subjects with chronic, treatment-resistant PTSD demonstrated that in the control group receiving psychotherapy with either inactive placebo or low-dose

MDMA, 22.6% no longer met diagnostic criteria for PTSD at the primary endpoint (two months after the final day-long experimental session). In the experimental group receiving psychotherapy with full-dose MDMA, 54.2% of subjects no longer met diagnostic criteria for PTSD at the primary endpoint. In the Phase 2 trials, each participant in the control group had the opportunity to cross-over to active, full-dose treatment. **At the one-year follow-up, 67% of all subjects treated with full-dose MDMA no longer met diagnostic criteria for PTSD, demonstrating the durability of positive treatment outcomes.**

MAPS is in the midst of conducting Phase 3 clinical trials, the large- scale, multi-site, pivotal studies required by FDA to determine whether or not a drug product is safe and effective for marketing approval

Over the past two years, MAPS has completed its first round of funding for the MDMA/PTSD program (\$34 million), trained 73 investigators in the therapeutic





model, initiated & completed an open-label lead-in study in which new investigators were trained while treating one PTSD patient, conducted Phase 3 start up and initiation, and began participant screening. Enrollment is currently ongoing at 15 sites across the United States (11), Canada (2), and Israel (2) for the first of two planned Phase 3 studies (MAPP-1, N=100).

In March 2020, an Independent Data Monitoring Committee (DMC) conducted an interim analysis by reviewing the outcome data from the first 60 subjects to be treated in MAPP-1. An interim analysis represents a make-or-break moment for a clinical trial, as the outcome provides a sponsor with the first clear signal of the likelihood of success. **The MAPP-1 interim analysis found that zero subjects needed to be added to the study to have a 90% or greater probability of obtaining statistically significant results.** With sufficient funding, MAPS is on track to have MDMA-assisted psychotherapy for chronic PTSD receive regulatory approval for prescription use, a landmark accomplishment for the promising field of psychedelic medicine. The Interim Analysis outcome demonstrates the viability of MAPS' drug development program, and sends a clear signal for full investment into the program based on industry standards.

About MAPS & PSFC

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 cannabis. MAPS is regarded internationally as a leading organization for responsible research, psychedelic harm reduction and advocacy, and as a clearing house for the growing knowledge base in the field of psychedelic science. Since its founding in 1986, MAPS has aimed to set a gold-standard for accessible, ethical, legal psychedelic-assisted therapy treatment through establishing global access to MDMA-assisted psychotherapy first for PTSD, then other indications, thereby paving the way for other psychedelic-assisted therapies. To date, MAPS has raised over \$93 million in donations and pledges to fund psychedelic research, advocacy and education.

Psychedelic Science Funders Collaborative (PSFC) is a 501(c)(3) nonprofit that supports research on and clinical trials of physician-prescribed psychedelic medicines and patient access to these treatments. Since its founding in 2017, PSFC has grown into a community of many of the leading philanthropists dedicated to supporting psychedelic medicine.

