

MAPS Research: A Year in Review

By: Valerie Mojeiko, Deputy Director



Valerie Mojeiko, B.A.
MAPS Deputy Director
valerie@maps.org

In the past year, we have greatly increased our capacity for designing, implementing, and monitoring MAPS' clinical trials around the world. We have learned that there is much work to be done even after a study is finished treating patients and the raw data arrives at our headquarters. As the end of the year draws to a close, I'd like to review some of the highlights of the past year, and give you a preview of the year to come in our clinical research department.

Highlights from 2009

Our flagship study of MDMA-assisted psychotherapy in the treatment of post-traumatic stress disorder in Charleston, South Carolina, which had the last subject's last visit in September 2008, has had all of the data entered into an FDA database, monitored, and locked. We conducted our first database audit on the weekend of October 17-18, 2009 and we passed this audit with an acceptable error rate of .425%. The pharmaceutical industry standard is .5%. This level of precision ensures that we do not report any false results due to incorrect data entry, and it creates an auditable trail in case the FDA decides to inspect our records.

MAPS Executive Director Rick Doblin, Ph.D. said of our flagship study, "It generated remarkably strong results. If we can replicate these results in our other studies, we can obtain approval by the FDA and the European Medicines Agency (EMA) for the prescription use of MDMA-assisted psychotherapy for PTSD."

In Switzerland, Peter Oehen, M.D. and Verena Widmer, R.N. have finished enrollment for their MDMA/PTSD study and are currently treating the 12th of 12 subjects. Back at MAPS headquarters, we have created a database for this study and are currently testing it. We plan to begin data entry for this study in February after our monitoring team conducts a visit to collect the study data.

Also in Switzerland, our study inves-

tigating LSD-assisted psychotherapy in the treatment of anxiety and depression associated with life-threatening illnesses has continued to enroll subjects. We hope to pass the halfway point of the treatment phase in 2010. The study has been receiving excellent media attention with articles in *Der Spiegel* and the *Guardian*.

We have been looking at all of our protocols with an eye toward ways to save money. With that in mind, we have removed some outcome measures that we determined were redundant, and we streamlined the materials given to the study sites for data collection. This will save us time and money conducting our studies and then again when we bring the data into our office to be monitored and entered into our database.

One of the largest costs for our studies is the therapists' time. Our psychotherapy model is very time intensive, with two professionals (one of them a medical doctor) spending eight hours or more with the patient during the experimental sessions with MDMA or placebo. We are exploring a new money-saving idea, utilizing a trainee or psychology intern as the study co-therapist, who is willing to work on a volunteer basis in exchange for the experience. We are considering testing this model out for the first time in Jordan, and if it is successful, we may adopt this model for our Phase 3 multi-site studies.

In September, we hired two outside contract research organizations (CROs)—

FDA Clinical Trials Sponsored by MAPS

Drug	Condition	Location	Principal investigator	Status
MDMA	PTSD	Charleston	M. Mithoefer, M.D.	Completed, Database Locked
MDMA	PTSD	Switzerland	P. Oehen, M.D.	Enrollment Complete, Treatment Phase in Progress
MDMA	PTSD	Israel	M. Kotler, M.D.	Currently Enrolling
MDMA	PTSD	Canada	I. Pacey, M.D. & A. Feldmar, Ph.D.	Pre-Initiation
MDMA	PTSD	Spain	J.C. Bouso, M.D.	Pending Grant
MDMA	PTSD	France	TBD	Pending Location Search
MDMA	PTSD	Jordan	TBD	Protocol Design and Approval
LSD	End of Life Anxiety	Switzerland	P. Gasser, M.D.	Currently Enrolling
Psiilocybin	End of Life Anxiety	Florida	S. Kumar, Ph.D.	Pending Location Search

The protocol will allow the Mithoefers to administer one MDMA session to therapists as part of their preparation for administering MDMA to PTSD subjects in our research protocols.

one in Israel and one in Jordan—to ensure that these studies are monitored with the same high standards that we employ closer to home. We hope that the difficulty of working with a 10-hour time zone difference and of monitoring study materials that are in Hebrew and Arabic (both of which not only use different alphabets than English but are read from right to left instead of left to right) will be greatly reduced by employing these CROs, which are each based in the study's respective country.

“We’re also seeing that our local CROs are helping us to understand cultural differences that we would otherwise have not noticed, so that we can proceed in a more sensitive manner,” said Rick. “Our international CRO’s work will free up more of MAPS’ clinical research staff time, since monitoring studies in the Middle East from our base in Santa Cruz is quite a challenge. This will leave us focused on the primary challenges of protocol design, regulatory approval, locating and training therapist teams, helping to recruit subjects, and fundraising.”

On the Horizon for 2010

We are excited to start several new studies in 2010.

In the U.S., we are working with Michael Mithoefer, M.D. and Annie Mithoefer, B.S.N. on two new studies in Charleston, South Carolina. We will be expanding on their previous PTSD study with a similar study that will be exclusively for veterans of war. Their previous study had enrolled 2 veterans out of a total of 21 survivors of other causes

of PTSD (mostly physical and sexual assault). This new protocol will test what is called a “three-arm design” with subjects randomized to low, medium or high doses of MDMA. This may become the study design we use in our Phase 3 multisite studies since we expect it will produce a successful double-blind with the therapists and subject being less certain of which dose they received.

The Mithoefers will also be spearheading an optional part of our standard therapist training program for our other co-therapist teams, under a protocol for which FDA has given us permission to proceed. The protocol will allow the Mithoefers to administer one MDMA session to therapists as part of their preparation for administering MDMA to PTSD subjects in our research protocols. This protocol is designed simultaneously to collect information on the psychological effects of MDMA in healthy volunteers who are administered one full dose of MDMA, and to provide an MDMA experience to therapists. Enrollment is limited to therapists who have completed our training program, which consists primarily of analysis of videos of actual MDMA/PTSD therapy sessions and critical discussions about our treatment manual and therapeutic method.

At the time of this writing, it looks as if we will begin recruitment in the early part of 2010 for a new MDMA/PTSD study in Vancouver, BC conducted by psychiatrist Ingrid Pacey, M.D. and therapist Andrew Feldmar, M.A. On October 24, 2009, we hosted a benefit in Vancouver to kick off the start of

Struggle Continues to Resume Marijuana Research

NEARLY a decade since we started our struggle to break the federal government's monopoly on the supply of marijuana for research, the U.S. DEA's strategy of delay continues to be successful and our efforts continue to leave us frustrated. On February 12, 2007, after extensive testimony, DEA Administrative Law Judge (ALJ) Mary Ellen Bittner wrote an 87-page ruling finding that it would be in the public interest for the DEA to issue a license to Prof. Lyle Craker, UMass Amherst, to grow marijuana for MAPS-sponsored research. However, the DEA's ALJ only issues recommendations to the DEA Administrator. On January 14, 2009, after almost two years of delay and just six days before President Obama's inauguration, the DEA issued a "Final Order" rejecting the recommendation and refusing to issue Prof. Craker a license. Due to some expert pro-bono legal work from the ACLU

Drug Law Reform Project and DC law firm Jenner & Block, we've challenged DEA's "Final Order" and entered a "Motion to Reconsider", which the DEA has not responded to at the time this went to press, months after the "Motion to Reconsider" was entered. On the one hand, we see the wisdom in waiting for a response to our "Motion to Reconsider" until after the Obama administration appoints new leadership at the DEA. On the other hand, we are deeply disappointed by the delay of justice and the DEA's obstruction of studying marijuana's medicinal risks and benefits. Meanwhile, the DEA's rejection of medical marijuana research is providing yet more motivation for additional states to move toward approving the medical use of marijuana, since the FDA drug development route is closed. For more information, see our DEA lawsuit documents at: www.maps.org/mmj/

the study, at which we brought together key decision makers from the region and raised over \$10,000. We expect the study to cost \$320,000 over two to three years.

In Jordan, our CRO is helping us to finalize the protocol and study materials before submission to regulatory agencies. We are looking forward to the challenge that this particular study will likely present, given that the two therapists conducting it are completely new to the idea of psychedelic psychotherapy and due to the study taking place in a culture much different than our own.

"I must say, I was impressed by the people and facilities there," said MAPS Medical Monitor Dr. Mithoefer, M.D.

who, along with Rick, met with the team on October 20, 2009 in Amman and presented information to representatives of the Jordanian FDA. We are excited to begin this study in 2010.

We now believe that once the MDMA/PTSD studies that are currently underway or in development are completed, we will have enough data to submit to the U.S. FDA for our End-of-Phase 2 meeting. If this meeting goes well, our next studies will be part of our Phase 3 multi-site trials -- the final round of studies in the quest to put MDMA back into the hands of therapists. •