Procedures for Conducting **Legal Psychedelic Studies**: MAPS Research Update

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People always ask me, "How do you DO this? How does MAPS give MDMA to people legally?" In this research report, I'd like to share with you some "behind the scenes" information about how we go through the process of starting a psychedelic study, and I'll also report on recent progress from each of our clinical trials under the US FDA.

Before we enroll our first subject, there are several things that must take place. The first stage is the contract negotiation phase. During this phase, delegates from MAPS clinical research department meet with the site team who is interested in hosting one of our studies. This is when we work out the details to find out whether it is feasible to do a trial together. Together we explore whether there is an appropriate location for the therapy to take place, an adequate subject population, qualified therapists, obtainable funding, and whether it is likely that the host institution (and country) will allow the study to take place.

If we agree that the relationship will work with the site, we move on to the protocol development and approval phase. This is when we have a series of conference calls and meetings in person between the MAPS clinical research department and the site to decide on critical design elements such as how many subjects will be enrolled, how many sessions will take place, drug and dosage, where the therapy will be conducted, and roles and responsibilities for the research team. Once the protocol is written we submit it to an institutional review board (IRB, also known as an Ethics Committee) who review it to safeguard the rights, safety, and well-being of the subjects. This process can take a lot of time and negotiation, often months. We also submit the protocol to all governing regulatory agencies and the principal investigator applies for licensure to administer the drug.

During the approval process, we begin our fundraising process. Once approved, the investigators begin enrollment, but this is not where MAPS' role ends. During enrollment we keep in close contact with the site to make sure the protocol is being conducted as planned and that standards of the International Council of Harmonization/Good Clinical Practice (ICH/GCP) are being met. As the sponsors of the research we continue to be of assistance to the investigators through documentation, review, support, and refining of methods in the treatment procedures.

Since we have had so many new studies springing up in the past two years, we have created a chart to show the progress at a glance. The Chart shows not only what studies are being conducted and where, but also where they are currently at in the approval or enrollment phase. (See chart page 12).

MDMA and Posttraumatic Stress

Our top priority line of projects right now are our studies of MDMA-Assisted Psychotherapy in the Treatment of Posttraumatic Stress Disorder (PTSD). So far, we have completed one study in the US; we have two studies that are currently enrolling subjects, one in Switzerland and one in Israel. We have four more MDMA/

FDA Clinical Trials Sponsored by MAPS

Drug	Condition	Location	Principal investigator	Status
MDMA	PTSD	Charleston	M. Mithoefer, M.D.	Completed, Reporting Results
MDMA	PTSD	Switzerland	P. Oehen, M.D.	Currently Enrolling
MDMA	PTSD	Israel	M. Kotler, M.D.	Currently Enrolling
MDMA	PTSD	Canada	I. Pacey, MD and A. Feldmar, Ph.D.	Protocol Design and Approval
MDMA	PTSD	Spain	J.C. Bouso, M.D.	Site/Sponsor Contract Negotiation
MDMA	PTSD	France	TBD	Site/Sponsor Contract Negotiation
MDMA	PTSD	Jordan	N. Shuriquie, M.D.	Protocol Design and Approval
LSD	End of Life Anxiety	Switzerland	P. Gasser, M.D.	Currently Enrolling
Psilocybin	End of Life Anxiety	Florida	S. Kumar, Ph.D.	Site/Sponsor Contract Negotiation

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PTSD studies in the works in Canada, Jordan, Spain, and France.

Since our last *Bulletin* was sent out, the Mithoefers completed the last visit for the last subject in MAPS' flagship study of MDMA-assisted psychotherapy in the treatment of PTSD. MAPS' research team has analyzed the results of the study and have found that they are statistically and clinically significant, so much so that we are comfortable speaking in terms of cures rather than just symptom relief. The results of our therapy are so far better than that of any currently available pharmaceutical medicine. We also have had an excellent track record of safety. Dr. Mithoefer presented the results of the study at the International Society for Traumatic Stress Studies conference and we are in the process of writing a paper for publication.

Our other MDMA projects around the world are also moving gradually toward completion. In Switzerland, Dr. Oehen is halfway finished with his study of twelve subjects. In Israel two subjects out of twelve have completed the study and several more have been enrolled.

We have completed our protocol for our newest site in Canada, and submitted it to an IRB. The protocol was approved by an IRB on November 5th and we are now submitting it to Health Canada, with a goal of enrolling our first subject in the Spring of 2009.

We have already drafted a protocol and negotiated a contract for our Jordanian study. By the time you are reading this *Bulletin*, the protocol will have likely been through the Jordanian ethics committee's first evaluation.

Our Spain and France studies are currently in the contract negotiation phase between the study site and MAPS. We will keep you posted as these potential studies progress.

As Dr. Mithoefer reported in our last *Bulletin* , we are also hard at work standardizing the therapeutic aspects of our treatment model by designing a manual, feedback process, and training program. This is essential as we move onto the next phase of clinical trials with the FDA.

LSD/Psilocybin and Anxiety

We are also excited to report that our LSD-assisted psychotherapy study in the treatment of anxiety secondary to life-threatening illness has treated two subjects and enrolled two others. This study, which is taking place in Switzerland under the direction of psychiatrist Peter Gasser, MD, will treat an eventual twelve subjects.

Also under development in the US is a study of psilocybin-assisted psychotherapy in the treatment of anxiety secondary to advanced stage melanoma. The FDA has approved this study, but we have not yet received IRB approval. This study will treat nine subjects at an academic and medical institution in South Florida.

Towards FDA Approval

All of the studies reported on above are being submitted to the US Food and Drug Administration so that the FDA will accept the data from the studies. We at MAPS believe that drugs like MDMA, LSD and Psilocybin have legitimate medical use,

and our studies aim to investigate this. If our research findings confirm this assumption and the FDA agrees, these drugs will become part of the pharmacopoeia, and will be available for specially trained health care professionals to use as part of their practice.

In my time at MAPS I have seen our first psychedelic therapy study in the US gain approval in 2003, and the ensuing bloom of our clinical research department. Now we have seen this first study to completion and the department is growing faster than ever. We are even planning to hire a Clinical Program Manager in 2009.

In order to continue this trajectory, our goals within the next two years are to have end-of-phase-II meetings with the FDA and the European Medicines Agency in order to helps us design our clinical trials for "FDA Phase III" multi-site studies. The phase III studies will require hundreds of subjects and dozens of research teams across the country and around the world. This is going to take a tremendous amount of resources, not only of money but also of therapist teams. If you or someone you know is interested in receiving information about conducting a clinical trial with MAPS in the next five years, please contact me at Valerie@maps.org and I will put you on our list.

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