

Setting Standards for MDMA-Assisted Psychotherapy Research:

MAPS' New Training Program for Therapists and Independent Raters

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THE PRIMARY GOAL OF MAPS' clinical development plan is to provide evidence for the safety and efficacy of MDMA-assisted psychotherapy for chronic, treatment-resistant PTSD. Our clinical trials aim to show that MDMA-assisted psychotherapy treatment is effective by achieving results that are measurable and reproducible as well as clinically and statistically significant. Achieving reproducible results across clinical studies requires us to standardize both our treatment methods and how we measure reduction in PTSD symptoms following therapy.

Standardized methods enable us to compare data across study sites, therapist teams, and subject populations, enhancing the reliability and accuracy of our results. MAPS has made significant progress in the area of standardization through the development of manuals, training programs, and criteria for evaluating adherence to the methods used in our international trials. Our new standardization programs are making it feasible to effectively train new generations of therapists and Independent Raters on our treatment and scientific methods

The principle measure we use to assess the effectiveness of our MDMA-assisted psychotherapy treatment is the Clinician-Administered PTSD Scale (CAPS). Clinicians and therapists worldwide use the CAPS to evaluate the severity of PTSD symptoms. Each of our clinical studies employs an Independent Rater not involved with the actual MDMA-assisted psychotherapy sessions. These Independent Raters do not know which treatment a participant receives during therapy (whether they received MDMA or placebo, high dose or low dose) and only sees the participant when it is time to measure PTSD symptoms.

In order to ensure that PTSD symptoms are measured consistently we have created a CAPS Training Manual for Independent Raters conducting the CAPS interviews in our PTSD studies, based on materials provided by the U.S. Veterans Administration (VA). The CAPS Training Manual is supplemented by video

tutorials of CAPS interviews, two supplied by the VA and the rest created from actual CAPS interviews with subjects enrolled in one of MAPS' clinical studies. Although the VA currently can only offer training on the CAPS to VA employees due to recent budget cuts, they have agreed to share the material with us. We have supplemented the VA training materials with additional instructions and videos to provide consistent training to all Independent Raters working on MAPS studies.

Another way we're working to standardize CAPS assessment across our international sites is by providing certified translations of CAPS interview questions in subjects' native languages. The process of creating a certified translation includes an original translation followed by back-translation into English to ensure that the meaning of the questions is preserved. By providing an official translation, we can ensure that Independent Raters

in other countries are able to ask participants CAPS interview questions in a consistent way. Without this, Independent Raters would need to translate the interview questions on the spot for each participant, creating inconsistencies in the way the interview is conducted. To date, we have translated the CAPS into both Hebrew and Arabic. Recognizing the utility of these translations, the National Center for PTSD has requested that we share the translations with them.

Our ongoing efforts to standardize MDMA-assisted psychotherapy treatment include the development of a Treatment Manual for conducting MDMA-assisted psychotherapy (www.maps.org/treatmentmanual). Much of the work involved in creating this document was done concurrently with our completed flagship Phase 2 pilot study in Charleston, South Carolina, by Michael Mithoefer, M.D., Rick Doblin, Ph.D., Lisa Jerome, Ph.D., June May Ruse, Psy.D., and Elizabeth Gibson, M.S. This detailed manual provides therapists conducting MDMA-assisted psychotherapy with standardized methods to ensure that each participant in our trials receives a similar treatment during each experimental session. In addition to providing training to clinical trial investigators, seminars on the Treatment Manual have been an integral part of public workshops conducted at MAPS events.

Defining our treatment methodology is as important as creating predefined criteria to evaluate how well therapists adhere to it. In MAPS' clinical studies, this is accomplished by assessing videos of actual MDMA-assisted psychotherapy sessions to evaluate whether therapists understood and followed the methodology defined in the Treatment Manual. We are currently using these adherence criteria to rate videos of therapy sessions from our ongoing study of U.S. veterans and our recently completed Swiss study. This same rating procedure will also be completed in all future studies to ensure adherence to the therapy manual across sites and therapist teams.

MAPS' newly established Adherence Criteria Workgroup will address growing need for accurate assessments of therapist adherence to our treatment method. This workgroup, which includes Linnae Ponte, B.S., Berra Yazar-Klosinski, Ph.D. and Katie Hendy, M.A., will develop an Adherence Criteria rating program and associated training materials. This will allow MAPS to continually monitor the effectiveness of our standardization techniques for MDMA-assisted psychotherapy. In addition to conducting ratings across multiple studies, the Adherence Criteria Workgroup will also train additional raters on how to assess adherence to our methodology.

By standardizing our therapeutic method, measurements of PTSD severity, and the methods by which we assess adherence to the Treatment Manual, we hope to minimize variation across multiple Phase 2 pilot studies in preparation for a meta-analysis of our Phase 2 data. Standardization is a crucial step before we move on to the larger Phase 3 studies required for federal approval of MDMA-assisted psychotherapy as a legal treatment for PTSD. •