Multidisciplinary Association for Psychedelic Studies
3141 Stevens Creek Blvd. #40563, San Jose, CA 95117
Phone: +1 (831) 429-6362 | Fax: +1 (831) 429-6370
maps.org

MJP2 Reporting Period Progress Report January 15, 2022

The applicant for this grant is the non-profit MAPS, with support from its wholly owned subsidiary and subrecipient the MAPS Public Benefit Corporation (MAPS PBC). As planned, MAPS PBC has spent the first 6 months of the project on start-up activities, dedicated to preparation of personnel, supplies, information systems, and clinical trial sites and staff for VMR purposes. Unfortunately, while conducting these activities MAPS PBC has encountered a significant delay for MJP2 study, with an estimated 5-month delay in timelines from initial projections. MAPS PBC had initially forecasted that site enrollment would begin by February 2022 but this has now been pushed to July 2022. This delay is due to the fact that the FDA has issued a continued a clinical hold on the study at the end of December 2021. MAPS PBC is in communication with the agency and working internally and with our study drug supply partner Aqualitas to address the FDA's concerns regarding the placebo cannabis for the trial.

In order to control costs during this delay, MAPS PBC personnel have slightly reduced their percent effort being billed to the direct and administrative costs whilst the regulatory and cannabis issues are being addressed. The Investigator Meeting costs have been delayed under the VMR Travel category of the budget based on this delay.

Meanwhile, subcontractor assessment and supply purchasing are actively progressing. The Oura rings have been purchased for the study. Contracting for the cannabis drug costs are underway. The vape devices have been obtained as a donation from Storz & Bickel America, Inc. MAPS PBC has completed the Contract Research Organization (CRO) selection and audit process. Alira Health has been chosen as our CRO subcontractor. The contract has been executed and the study team has been selected. The CRO is commencing site qualification activities for the subcontractors representing Clinical Sites 1-4.

MAPS PBC has conducted a thorough assessment and decided not to subcontract with the sole source contractor Analgesic Solutions for placebo response reduction training for our study. Given our deep understanding of clinician-administered endpoints and our existing Independent Rater infrastructure we have decided to develop placebo response minimization procedures with support from the MAPS PBC Independent Rater Pool for this task. Funds allocated for Analgesic Solutions would be reallocated to reimburse for the additional Independent Rater Pool time & effort.

Additionally, further discussions with Syqe Medical has led to the decision not to utilize their services for GMP cannabis packaging and processing of the Syqe Inhaler at this time. Incorporating the Syqe inhaler into our study would introduce confounding variables and mitigation would have required an extensive study redesign with the potential to greatly increase timeline and budget. Furthermore, the use of this device would have moved us away from the intent of studying Real World Use of cannabis currently available in the United States. Since Syqe will no longer be involved, funds will be reallocated to pay for the cost of a different vendor to package and label the botanical cannabis for the study.

Over the next reporting period, the negotiations with the FDA will continue in order to obtain clearance and activate the federal IND for inhaled botanical cannabis for the trial. The CRO Alira Health will continue site qualification activities at the identified clinical sites and begin the contract and budgeting process at the clinical trial sites. The regulatory files will be set up and study template documents will be created and procedural manuals written. Case report forms will be designed and the database will be built. IRB submissions will begin once we receive regulatory approval to proceed.