MJP2 Quarterly Progress Report – Q3 2023
October 15, 2023

1. % of completion and work done during project period:

A) % of Completion:

MAPS has performed approximately 5-10% of the work initially proposed in the statement of work.

B) Work Completed During Project Period - Clinical Hold Status Update:

As previously described, MAPS conducted a successful Type A meeting with the FDA Division of Psychiatry on June 15, 2023. The official meeting minutes were provided by FDA on July 12, 2023 noting the progress and agreements that were made during the meeting. However, a number of the outstanding issues were in the scope the Division of Pulmonology, Allergy, and Critical Care (DPACC) who did not attend the June 15th meeting. Instead, they provided comments in a separate post-meeting communication on August 11, 2023. These comments reflected a lack of understanding between the differential risks of tobacco and marijuana smoking as well as between dried botanical vaporization and "e-cig" cartridge vaporization. The next step in the efforts to remove the clinical hold is a formal "Clinical Hold Response." MAPS drafted this updated Clinical Hold Response and updated protocol incorporating the recent updates in the meeting minutes from the June Type A meeting as well as the DPACC post-meeting comments. MAPS is further including additional accommodations in this proposal in an effort to address the reasonable concerns of FDA, while ensuring maintenance of the critical real-world elements of the proposal that make this data collection meaningful. The Clinical Hold Response and updated protocol are undergoing final revisions in preparation for formal submission to the FDA Division of Psychiatry at the end of October. MAPS anticipates receiving a response from FDA to this proposal 30 days from the final submission date.

2. Description of Problems and Delays:

MAPS continues to work to resolve the FDA clinical hold and continue trial activities.

3. Statement regarding any deviation from SOW:

A) Project Change Request - Personnel and Contractual Services:

As detailed above, MAPS is working to resolve the FDA clinical hold and continue trial activities. MAPS had previously delegated the oversight and conduct of this trial to its subsidiary, MAPS PBC. As the hold has progressed, it became necessary for MAPS PBC to reallocate large portion of personnel resources to the organization's other clinical research including the completion and of a confirmatory Phase 3 trial of MDMA-assisted therapy for the treatment of PTSD. MAPS PBC announced the intention of submitting a New Drug Application for the drug-therapy combination to the FDA in the coming year which required MAPS PBC personnel to focus on these efforts. To ensure the continued progress on this grant to both lift the clinical hold and start up the clinical trial, MAPS is now directly overseeing and conducting this work and no longer delegating the trial oversight and conduct to MAPS PBC.

In order for MAPS to continue the MJP2 research, MAPS is proposing to shift the proposed budget from the specified internal personnel to both expand the role of the Contract Research Organization (currently Alira Health), as well as incorporate additional contracted service providers to fulfill needs related to CMC, Regulatory Affairs, and Independent Rating. MAPS' immediate focus continues to remain on resolving the FDA clinical hold. We are requesting the approval of these budget modifications to support our work in obtaining the required information and developing a formal response, both of which are necessary for FDA to remove the clinical hold. Additionally, the budget modifications allow us to begin the process of vetting additional contracted support and selecting contracts as needed. A summarized list of project changes and the associated budget changes can be found below. Additionally, we have provided a proposed updated budget for your review which indicates the original budgeted amounts, amount spent to date, and newly proposed budget amounts.

- **Chemistry, Manufacturing and Controls (CMC):** MAPS has thus far already shifted $32,032 that was budgeted for CMC personnel (Program-Personnel) to a CMC contractor, we are requesting to shift an additional $75,000 for further contracted CMC support, bringing the total to $107,032.
- **Regulatory Affairs:** MAPS is requesting that $250,000 be shifted from the Program-Personnel budget to Program-Contracted Services to be used for Regulatory Affairs support.
- **Contract Research Organization:** MAPS is requesting to shift $3,527,036 from the Program-Personnel, Program-Supplies, and Program-Contractual Services budgets to cover the cost of expanded Contract Research Organization services, bringing the total to $5,500,000
- **Independent Rater Pool:** MAPS is requesting to shift $231,200 from the Program-Personnel and Program-Supplies budgets to cover the cost of contracted Independent Rater services, bringing the total to $980,000.
- **Study Drug and Placebo:** MAPS is requesting to shift $100,000 from the Program-Supplies budget to cover the updated costs of the study drug, placebo, and stability studies, bringing the total to $150,000.
- **Administrative/Indirect Expense:** MAPS is requesting to shift $500,000 from the Admin-Personnel budget to the Indirect Expense budget to cover a portion of MAPS' essential infrastructure and operating costs, including Human Resources, IT, Accounting, and Legal services; technology and software; insurance; and office expenses.

B) Project Change Request - Grant Term:

MAPS' original Work Plan describes a sponsored clinical trial planned as a 35-month project, commenting with Last Patient, Last Visit (LSLV) in December of 2023 and the final Clinical Study Report filed to the FDA in 2024. The FDA clinical hold persisting from 2022 into 2023, has greatly affected this proposed timeline for initiating the study sites. If the FDA clinical hold is removed by the end of 2023, and the original study duration assumption stays the same, study completion would take place near the end of 2026. MAPS requests clarification as to whether the Grant Period can be extended to carryover allocated funds in order to accommodate the completion of the clinical trial.

4. Quarterly Financial Expenditures:

During this reporting period, MAPS has billed $19,878.82 in administrative support of the VMR program for administrative information systems and administrative personnel. VMR Program expense in Q2 totaled $47,874.08. Total expenditure to date equal 10% of the total contract value.