Multidisciplinary Association for Psychedelic Studies
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maps.org

MJP2 Reporting Period Progress Report – Q2 2023
July 15, 2023

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

MAPS has performed approximately 5-10% of the work initially proposed in the statement of work (SOW). During the current reporting period, we continued our efforts to find a suitable study design for FDA that would also meet the goals set out in our proposal to study cannabis use that is relevant to the real-world use of veterans. In this reporting period we developed an updated protocol reflecting these goals that temporarily removed the vaporizer and water pipe devices from the protocol and utilize a smoking only protocol – like that which was previously cleared by FDA in MAPS' first cannabis study (MJP-1). In keeping with FDA encouragement to schedule a formal meeting to discuss the protocol submitted this updated protocol, we developed a formal meeting request for a Type A meeting and formal meeting briefing packet (as required by FDA to conduct a meeting). The Meeting Briefing Packet outlines the topics we intended to discuss with FDA and the rationale to support our proposed outcome. These were submitted to the FDA, along with the updated protocol, on April 28, 2023. In keeping with our values of transparency and to support other research teams going through similar review processes with FDA, our team also posted this submission publicly on the MAPS website (https://maps.org/2023/04/28/maps-requests-fda-for-a-type-a-meeting-to-discuss-clinical-hold-for-the-phase-2-study-of-cannabis-for-veterans-with-ptsd-mjp2/)

On May 9, 2023, the FDA granted our request for a meeting which was scheduled for June 15. Our team worked to prepare for the meeting and respond to the FDA's concerns about our proposals. As reported in our previous quarterly report, the concerns raised by the FDA are a result of our innovative protocol design centering real world dosing and administration of cannabis, which has not been previously permitted under FDA reviewed protocols. Our current regulatory strategy is to retain as much of this critical real-world design as possible while compromising elements to permit the FDA to more quickly remove the clinical hold. Because this study uses cannabis that reflects the potency used in real world medical cannabis programs which is higher than previous trials, the FDA expressed a safety concern with the potential maximal dose of THC that could be administered. To overcome this safety concern, MAPS proposed to limit the maximum consumption in a short period, while retaining the overall potency and dosing.

The MAPS team met with the FDA on June 15 to discuss the questions on the protocol and try to develop a path forward for the protocol to meet the needs of the study. In the meeting the MAPS team highlighted the differences between a study designed to approve a specific formulation and precise dose of a drug, as is more standard for the FDA, and the proposal to model the dosing and administration to reflect the current use of medical cannabis (including more typical THC concentrations and varying doses and timing as titrated by the patient). Anton Harb also joined MAPS during this FDA meeting, volunteering his time to provide a patient testimony of the real world need for better research and data on medical cannabis experienced by veterans in Michigan. This conversation was fruitful and promising, and we believe that a path forward can be found that allows FDA to focus on ensuring safety without forcing the study design into a drug development paradigm. The official minutes reflecting the FDA stance and comments will be released by the FDA in Q3 2023. This will allow us to address the outstanding concerns and hopefully gain clearance for the trial.

In parallel, we are working with the drug manufacturers (Aquilitas and NIDA) to provide the outstanding testing and stability data, requested by the FDA, which will also be required to remove the clinical hold. While NIDA is currently updating their stability data for their cannabis, many clinical trials using NIDA cannabis have been put on hold with the FDA until these updates are completed. Stability testing is required to be in the final drug product form that will be supplied to participants during the study and must be developed specifically for this program. Stability data is standard and will be necessary throughout the study term. Aquilitas has begun a stability testing round of the final drug product format proposed and we expect to have the data from this testing in Q3 2023.

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2. Description of Problems and Delays:
As detailed above, MAPS is working to resolve the FDA clinical hold and continue trial activities.

3. Statement regarding any deviation from SOW:
The project's timeline continues to deviate from the SOW due to the issues noted above with the ongoing clinical hold. MAPS is committed to gaining FDA clearance for a protocol that is as close as possible to the SOW and will continue to provide updates on our efforts to gain FDA clearance for the trial.

4. Quarterly Financial Expenditures:
During this reporting period, MAPS has billed $19,132.14 in administrative support of the VMR program for administrative information systems and administrative personnel. During this reporting period Betty Aldworth completed administrative activities in support of Rick Doblin. Additionally, Allison Coker's Regulatory Affairs activities were more consistent with VMR Program activity, previously managed by Julie Blaisdell, and have been classified as VMR Program Personnel expense in Q2. VMR Program expense in Q2 totaled $21,046.24. Total spend to date equals 9% of the total contract value.