Multidisciplinary Association for Psychedelic Studies
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MJP2 Reporting Period Progress Report (5) – Q1 2023
April 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). As reported in our previous quarterly report, in September 2022, an FDA response was received which requested a full protocol amendment prior to reviewing a release on the clinical hold. A protocol amendment was developed and returned to the FDA in November. At the end of December, we received a response from the FDA indicating the continuation of the clinical hold, citing '21 CFR 312.42(b)(2)(i): Insufficient information to assess risks to human subjects' in our proposed protocol. In this reporting period, we have heavily focused our time on developing an FDA "Type A" meeting request strategy and briefing packet to be delivered to the FDA for this meeting.

While the continued clinical hold status discouraging, it is 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. One critical hold element related to the absence of device information on the vaporizer and water pipe the protocol proposed to provide to participants as delivery options. Because the FDA requires detailed product information on investigational devices that are used in clinical trial protocols, which is not currently available, we are proposing to temporarily remove the vaporizer and water pipe devices from the protocol and utilize a smoking only protocol - like what was previously cleared by FDA in MAPS' first cannabis study (MJP-1). We believe that this should resolve this hold issue and facilitate a more expeditious removal of the clinical hold.

Additionally, 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 is proposing to limit the maximum consumption in a short period, while retaining the overall potency and dosing. We believe this should resolve both hold issues regarding the maximum dose and self-titration. The first draft of the meeting briefing was completed at the end of March 2023 and is undergoing final review prior to submission. We plan to submit the meeting request in April 2023 for a Type A meeting targeted for May 2023.

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. 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.

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.

During this reporting period, Dr. Mark Kindy of the James A. Haley VA Medical Center notified MAPS of their intent to no longer serve as a clinical trial site once the FDA clinical hold has been lifted. Dr. Kindy indicated that an administrative decision was made to no longer support clinical trials using Schedule I substances James A. Haley VA Medical Center. Dr. Kindy, who also holds affiliation with the University of South Florida (USF), has indicated an interest in transferring the site responsibilities to USF instead.

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In comparison to "Attachment A: VMR Budget" submitted August 2nd, 2021, the following Administrative personnel changes or assignments have taken place during the course of this reporting period due to staff turnover, new hires, and/or project re-assignments: Erin Tasman has assumed responsibilities previously assigned to Drew House; Ryan Barnes has assumed some responsibilities previously assigned to Jami Murphy; Emily Williams has assumed some responsibilities previously assigned to Jami Murphy; Matt Clark has assumed some responsibilities previously assigned to Jane Zahniser and Mike Ruggles; Fede Menepace has assumed some responsibilities previously assigned to Rebecca Matthews; John Poncini has assumed some responsibilities previously assigned to Andrew Marty; Jennifer Ellis has assumed some of the responsibilities previously assigned to Erica Scott; Desiree Lopez has assumed some of the responsibilities assigned to Jami Murphy and Jamelia Avalos.

4. Quarterly Financial Expenditures:

During this reporting period, MAPS has billed $35,790.66 in administrative support of the VMR program for administrative information systems and administrative personnel. Administrative personnel directly supported the program by communicating with and coordinating investigators, trial sites, and contractors; performing regulatory duties and preparing for the Type A meeting with the FDA; and administering the grant.

5. Corrections to Previous Reports:

During this reporting period MAPS conducted an internal audit of VMR program expenses incurred through December 31st, 2022. In doing so, we uncovered corrections were needed for the reports submitted in September 2022 and January 2023. Included in this report, we have provided corrected quarterly financial reports, and below, we have provided a summary of the corrections made. These corrected reports were provided to the Grant Administrator, David Harns, on March 9th, 2023.

- A reimbursement from Alira health was mistakenly omitted from the Sept 30th report, causing us to over-report the total spend with Alira during this reporting period. This was corrected in the Sept 30th report and is also reflected in the January 15th report. Additionally, the method in which we were reporting Alira's spend in the Sept 30th report was unnecessarily complicated, it is now simplified to only show cash out.
- An invoice paid to Rudra Solutions was mistakenly tagged as an expense with Alira, this has been corrected to reflect accurate totals for each contractor for the Sept 30th report which is also reflected in the January 15th report.
- Allison Coker was mistakenly included as a "VMR Program Staff" expense, when she should have been listed as "Administrative Personnel," this has been corrected for the Sept 30th report which is also reflected in the January 15th report.
- Leading up to both reports, we had been incurring Administrative costs which, do to a simple misunderstanding, were omitted from the first two reports. We have audited these expenses to ensure compliance with the approved grant budget and have included the cumulative and quarterly Administrative spend in the Sept 30th report, which is also reflected in the January 15th report. The total expense incurred/billed through September 30th is only 9% of the allowable administrative total of the grant, much below the budget forecasted for this period, and as previously reported we did not bill any administrative expenses in Q4 of 2022.