Multidisciplinary Association for Psychedelic Studies
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MJP2 Reporting Period Progress Report July 15, 2022

The contracted agent for this grant is the Multidisciplinary Association for Psychedelic Studies (MAPS) with support from its wholly owned subsidiary and contract subrecipient, the MAPS Public Benefit Corporation (MAPS PBC).

During the first two reporting periods of October to December 2021 and January to March 2022, MAPS PBC reported significant progress on project start-up activities but also reported a five-month projected delay in trial start-up timelines. This delay was due to a clinical hold on the trial issued by the FDA at the end of December 2021. As communicated in the prior progress updates, the trial has not yet received FDA clearance to proceed.

Between January and March 2022, MAPS PBC focused on addressing the agency's concerns regarding the placebo cannabis originally considered for use in the trial. For support, MAPS PBC contracted Harpreet Kaur, PhD, of Rudra Solutions, Inc. Dr. Kaur is a well-known expert in the cannabis industry with extensive pharmaceutical research and development experience. To address the FDA's reasons for a clinical hold, Rudra Solutions recommended that MAPS PBC consider a new drug supply vendor with broader capabilities and ability to produce cannabis flower according to Good Manufacturing Practices (cGMP) to supply both the cannabis and placebo products. MAPS PBC had identified a strong prospective cannabis supplier; however, in April 2022, the vendor suddenly disengaged from sales conversations. Because of this, and the subsequent and unforeseen need to renew the search for a vendor, our anticipated May target for submitting the clinical hold response to the FDA, as well as the expected enrollment of the first trial participant, has been pushed back.

During this reporting period, of April to June 2022, MAPS PBC continued to focus on identifying a suitable cannabis supply vendor to satisfy FDA's concerns. With the assistance of Rudra Solutions, MAPS PBC made substantial efforts toward identifying a supplier with available cannabis flower produced according to current Good Manufacturing Practices (cGMP). Per FDA requirements, the cannabis and placebo products must have accompanying stability data to determine shelf life and storage conditions. If the vendor does not currently have stability data available, the vendor must commit to provide three months of data prior to the start of the trial and conduct ongoing testing and provide updated stability data as it becomes available. The prospective vendor must also have the necessary equipment and validated methodology to produce pre-rolled cannabis cigarettes to strengthen the blind of the trial. Because the cannabis industry is still relatively immature, there are very few cannabis suppliers with the required capabilities.

This has made the selection of suitable drug supply vendor an unexpected challenge. MAPS PBC contacted and/or evaluated 12 potential supply vendors between January and June 2022. Of the 12, eight were rejected due to a lack of response or concerns regarding capabilities. MAPS PBC is awaiting analytical and stability testing data and method validation documentation from the remaining four potential vendors to assess viability.

Receipt of the critical potency and stability data information from the potential drug supply vendors is still pending but is anticipated by the end of July 2022. Upon receipt of acceptable data, MAPS PBC will make a final vendor selection and submit a response to the FDA's clinical hold (August 2022). Following submission, a response from the agency is expected within 30 days (September 2022). Once the FDA has responded, all requested protocol modifications will be incorporated into a protocol amendment and submitted back to FDA for approval.

Following FDA clearance of the protocol amendment (estimated 30-60 days), the protocol will be submitted to the central Institutional Review Board (IRB) and clinical trial site institutional review committees and IRBs for approval to conduct the trial. Protocol amendment finalization, central IRB submission, and distribution of the amendment to clinical trial sites for institutional review committee submissions are targeted for December

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2022. This pushes target enrollment of first participant enrolled to the trial to the second quarter of 2023.

Over the next reporting period, MAPS PBC will continue to minimize direct and administrative costs by billing personnel costs at a reduced rate. Investigator Meeting costs under the VMR Travel category of the budget will remain deferred and collaboration with the Contract Research Organization (CRO) temporarily reduced. Full trial start-up work will resume once the protocol amendment has been finalized.

Subcontractor assessment is still actively underway. MAPS PBC's Chemistry, Manufacturing, and Controls (CMC) team are currently discussing cannabis drug costs with the newly identified potential supply vendors and selection of the packaging and distribution vendor remains ongoing.

The MAPS PBC clinical operations team continues to meet regularly with the CRO to create templates for trial documents, procedural manuals, and operational plans, all of which are needed to support the trial development. The CRO has been in communication with each clinical trial site to schedule a Site Qualification Visit (SQV) to ensure the sites have qualified personnel and adequate facilities to perform the trial. Following the first SQV conducted by the CRO in April 2022, qualification activities were put on hold to control costs but will recommence in July 2022. The remaining SQVs are targeted for completion by the end of Aug 2022. Contract and budget negotiation activities at the identified clinical trial sites will begin following site qualification.

MAPS PBC will continue to negotiate with the FDA to obtain clearance to conduct the trial and activate the federal Investigational New Drug (IND) Application for inhaled botanical cannabis. Following FDA clearance of the protocol amendment, clinical trial sites will submit the protocol to the central Institutional Review Board (IRB) and institutional review committees and IRBs for approval to conduct the trial.

While unanticipated delays have impacted the initially proposed timeline, MAPS PBC remains committed to launching this trial as quickly as is feasible. MAPS PBC will make every effort under its control to shorten the above timelines and expects to make meaningful start-up progress during the upcoming quarter.