Multidisciplinary Association for Psychedelic Studies
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MJP2 Reporting Period Progress Report April 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). As planned, MAPS PBC spent the first six months of the project on start-up activities, dedicated to the hiring and training of personnel including staff Veteran's Marijuana Research grant, sourcing and purchasing of study supplies, development of information systems, and establishment of clinical trial sites. While MAPS PBC reported considerable progress during this time, a projected delay of five months was also reported in trial start-up timelines. The delay moved the estimated start of participant enrollment from February 2022 to July 2022. As previously communicated, this delay was caused by a clinical hold on the trial as issued by the FDA at the end of December 2021. This has resulted in the study not yet receiving FDA clearance to proceed.

To avoid any further delays, during this reporting period of January to March 2022, MAPS PBC has focused it's efforts on addressing the FDA's comments. Significant efforts have been made toward addressing the agency's concerns regarding the placebo cannabis originally considered for use in the trial, ensuring the suitability and preferability of the route of drug administration for Veteran participants. In order to satisfy FDA's concerns, MAPS PBC has engaged a consultant who is well-known in the cannabis industry as an expert on the chemical science of cannabis, plant structure, and cultivation and production of cannabis flower. The consultant also has extensive research and development leadership experience in the pharmaceutical industry. The consultant has recommended that the 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. With the consultant's assistance, MAPS PBC has conducted a new vendor search and identified a prospective cannabis vendor with available cannabis flower produced according to cGMP. Per FDA requirements, this product has accompanying long term stability data to determine shelf life and storage conditions. The prospective vendor also has the necessary equipment and methodology to produce pre-rolled cannabis cigarettes to strengthen the blind of the study. At our request, the vendor is currently conducting analytical experiments to produce a suitable active placebo product for the purposes of the trial.

These efforts have caused an unforeseen, but essential, delay in the launch of the trial. Receipt of the critical potency and stability data information from the vendor is still pending but is anticipated by the end of April 2022. MAPS PBC intends to submit the clinical hold response to the FDA at the end of May 2022, and a response from the agency is expected within 30 days (end of June 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 are targeted for mid-to-late September 2022. This pushes target enrollment of first participant enrolled to the trial to first quarter of 2023. Every effort within MAPS PBC's control will be made to shorten the above timelines.

To control direct and administrative costs during this delay, MAPS PBC will continue to bill personnel costs at a reduced rate. Investigator Meeting costs continue to be delayed under the VMR Travel category of the budget. Collaboration with the biometrics group at the Contract Research Organization (CRO) has been suspended and further activities halted until the protocol amendment can be finalized.

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Subcontractor assessment and supply purchasing are still actively underway. Within the reporting period, vape devices and mobile devices have been obtained for the trial. Discussion of the cannabis drug costs with the potential supply vendor is underway, and selection of the packaging and distribution vendor is also in progress.

The MAPS PBC clinical operations team has established regular team meetings with the CRO and have begun working on trial documents and operational plans needed to support the trial, including contract and budget templates, project management plans, and filing plan for essential regulatory documents. The CRO has also been in communication with all clinical trial sites to schedule Site Qualification Visits (SQV) to ensure sites have qualified personnel and adequate facilities to perform the trial activities and to obtain regulatory review and start-up activity timelines. The CRO conducted one SQV in April 2022, and the remaining are targeted for completion by the end of May 2022.

Over the next reporting period, negotiations with the FDA will continue to obtain clearance and activate the federal Investigational New Drug (IND) Application for inhaled botanical cannabis for the trial. The CRO will continue qualification and contract and budget negotiation activities at the identified clinical trial sites. Creation of trial template documents and procedural manuals will continue. Case report forms will be designed in preparation for development of the clinical trial database. Training of the internal and CRO trial teams will begin, as will the creation of training materials for clinical trial site staff and resources for participants. IRB submissions will begin once FDA approval to proceed has been received and the protocol amendment finalized. While delays have impacted the original proposed timeline for the trial, we remain optimistic about our ability to make considerable progress this quarter.