Multidisciplinary Association for Psychedelic Studies
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MJP2 Reporting Period Progress Report (4) October 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).

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

Given the unanticipated delays that were beyond our control, we have unfortunately only been able to perform approximately 5-10% of the work initially proposed in the statement of work (SOW). MAPS PBC remains committed to launching this trial as quickly as is feasible and will continue to be diligent to lower our financial footprint and make every effort under its control to ensure that meaningful progress is made to move the project forward and achieve our deliverables.

During this reporting period, start-up activities have been ongoing to facilitate study start up as soon as the clinical hold is removed. The current work has included CRO performances of two additional Site Qualification Visits (SQV), (bringing the total to 3 completed with the final and 4th site will not go forward until study protocol has been finalized) negotiating CDA's, initiation of draft plans including monitoring and project management as well as site contract and budget templates.

Also in the last progress update, we explained the number of cannabis manufactures our Chemistry, Manufacturing and Controls (CMC) department contacted to support the IP and Placebo manufacturing. Of those 15 that were contacted, we have now retained a Letter of Authorization to cross-reference the Drug Master File (DMF) from the supplier for Placebo with another confirmed for the Active Cannabis product. We also have retained two backup suppliers.

2. Description of Problems and Delays:

During this reporting period of July 1 to September 30, 2022, efforts to address the FDA requirements and expectations to secure approval for this interventional clinical trial continued. These efforts are required to obtain regulatory clearance to conduct the trial and activate the federal Investigational New Drug (IND) Application for inhaled botanical cannabis. A majority of the FDA's Clinical Hold response addresses items such as dosing regimen, route of administration, and identification of vendors for active drug and placebo product. On August 16, 2022, MAPS PBC submitted a detailed response to the FDA in anticipation of a positive response and release of clinical hold. On September 28, 2022, the FDA response was received requesting a full protocol amendment before they would begin review to our latest submission. MAPS PBC is urgently moving forward with that amendment which is currently in its final stages of review internally. We anticipate this amendment to be finalized and returned to the FDA by early November 2022. Until MAPS PBC can secure clearance and the clinical hold is removed, any non-clinical hold related items will be tabled and updated in the future.

3. Statement regarding any deviation from SOW:

At this reporting period, the project has deviated from the SOW due to timeline impact from the issues noted above with the ongoing clinical hold.

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4. Quarterly Financial Expenditures:

MAPS PBC will continue to minimize direct and administrative costs and be good stewards of the CRA grant monies provided to us for this project. As a result of our review, we have decreased the number of CRO engagement meetings to limit costs during this clinical hold period and we have negotiated reimbursement for medical monitor related fees.