



Multidisciplinary Association for Psychedelic Studies
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Maps

MJP2 Quarterly Progress Report – Q3 2024

October 15, 2024

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

A) % of Completion:

MAPS has performed approximately 10-15% of the work initially proposed in the statement of work.

B) Work Completed During Project Period - Clinical Hold Status Update:

As previously described, MAPS developed an extensive formal response to the 4th Partial Clinical Hold in Q4 2023. This in-depth, 28-page response and protocol amendment addressed and incorporated the previous communications and discussions with the FDA, including the June 2023 Type A meeting with the FDA Division of Psychiatry and the post-meeting communication provided by the Division of Pulmonology, Allergy, and Critical Care (DPACC), while directly addressing the Clinical Hold Comments received from the FDA. MAPS addressed each point of scientific evidence and literature provided by the FDA, speaking to the strength and merit of the presented evidence, and provided additional scientific and data-driven literature to support the proposed dosing and administration paradigms in the protocol.

Despite this substantive submission, the FDA issued the 5th Partial Clinical Hold on our Phase 2 Study of Cannabis for Veterans with PTSD (MJP2) on December 28, 2023. This clinical hold letter rejected the study of smoked marijuana and vaporized marijuana without addressing any of the substantive responses in the Complete Response to the clinical hold submitted by MAPS in November 2023.

In Q1 2024, MAPS consulted with regulatory advisors to determine the most effective pathway forward to address the clinical hold. Due to the lack of substantive engagement from the Division of Psychiatry on the merits of the November response and the rejection of the study of smoked or vaporized marijuana, MAPS determined it was necessary to appeal this decision to the Office of Neuroscience through a Formal Dispute Resolution Request (FDRR).

In Q3 2024, MAPS collaborated with the selected vendor, Hyman, Phelps, and McNamara (HPM), to submit the FDRR to the Office of Neuroscience. The FDRR was based on both regulatory review standards and the scientific research data cited by MAPS in the prior Complete Response which were not addressed by the Division of Psychiatry. The FDRR asks the overseeing Office of Neuroscience to review this evidence and the risk:benefit ratio of the proposed research to allow Study MJP2 to proceed. The Office of Neuroscience responded to the FDRR at the end of Q3 2024, and MAPS is working with the agency to implement new updates to the protocol in a continued effort to remove the Clinical Hold. Given the productive correspondence in this quarter, MAPS submitted an updated protocol and ICF based on the FDA feedback in Q4 2024 (October 10, 2024) requesting the removal

of the clinical hold.

As an expression of our mission and values, MAPS will continue to practice transparency regarding the clinical hold process to ensure that the public has access to pertinent information about FDA policies and practices, as well as summaries of cutting-edge literature on cannabis safety. These resources provide an educational case study in regulatory negotiations for researchers and patient advocates in any discipline, and most importantly, ensure that current and future cannabis researchers can build upon our efforts to support more systematic and rigorous research into real-world cannabis use, which is currently grossly lacking. Following the conclusion of this process, MAPS will publicly post the FDA submissions and responses on our website. See here for all the prior submissions related to this program: <https://maps.org/marijuana/mjp2/>.

MAPS has been in communication with the VMR to amend the budget according to substantial and necessary changes in program management and the necessity of additional regulatory and CMC support to address the ongoing FDA clinical hold issues. MAPS initially requested a budget amendment and update to the grant terms in the Q3 2023 report submitted October 15, 2023. As previously reported, MAPS subsequently fulfilled additional requests to provide the VMR with supplementary information to review and approve the budget amendment request. MAPS and the VMR executed the contract amendment on August 21, 2024.

While MAPS' priority is the removal of the clinical hold, MAPS continues to judiciously manage the vendors that were previously identified through competitive bidding processes to both ensure that undue expenses are not committed prior to the clinical hold being lifted and that there are no unnecessary delays during the study start-up period once the clinical hold is removed. To this effect, MAPS executed a Master Services Agreement and Quality Assurance Agreement with the CMC vendor for the active cannabis product in this quarter. MAPS also initiated a review of the contracts with the CRO, Alira Health Clinical, LLC, to prepare to renegotiate the existing contract in preparation for study start-up. The contract needs to be renegotiated since many responsibilities previously delegated to Lykos Therapeutics (formerly known as MAPS PBC) will be delegated to contractors, as described below.

2. Description of Problems and Delays:

MAPS continues to work to resolve the FDA clinical hold and continue trial set-up activities.

3. Statement regarding any deviation from SOW:

Project Change Request: Personnel and Contracted Services

As documented in the initial approved grant budget, overall project and program management was delegated to Lykos Therapeutics (formerly MAPS Public Benefit Corporation) and a CRO was selected to primarily oversee trial site conduct while Lykos conducted the internal Sponsor roles. However, at the end of 2022, Lykos reallocated a significant amount personnel resources to the organization's other clinical research efforts including an NDA submission for MDMA-assisted therapy for the treatment of PTSD and informed MAPS that they would no longer be able to act as delegate of Sponsor roles on this program.

As of Q1 2023, MAPS is directly overseeing and conducting this work and no longer delegating the trial oversight and conduct to Lykos. Given that MAPS staff does not have the scope of internal positions needed to take over the functions delegated to the Lykos "internal program staff" or the infrastructure to host the information systems, data, and trial recruitment, many additional responsibilities will need to be delegated to contractors.

Therefore, MAPS proposed in the Q3 2023 report submitted 15Oct2023 to amend the proposed budget in order to shift funds from the specified internal personnel to both expand the role of the external functions, specifically the Contract Research Organization (currently Alira Health) and incorporate additional contracted service providers to fulfill the previous internal Lykos roles related to CMC, Regulatory Affairs, and Independent Rating. As previously reported, MAPS subsequently fulfilled additional requests to provide the VMR with supplemental information to review and approve the budget amendment request. MAPS and the VMR executed the contract amendment on Aug 21, 2024.

A) Project Change Request – Grant Term:

MAPS' original Work Plan described a sponsored clinical trial planned as a 35-month project, commenting with Last Patient, Last Visit (LSLV) in December of 2023 and the final Clinical Study Report filed to the FDA in 2024. The FDA clinical hold persisting from 2021 into 2024 has greatly affected this proposed timeline for initiating the study sites. On August 21, 2024, MAPS and the VMR executed a contract amendment which included formally extending the Grant Period to December 31, 2027.

4. Quarterly Financial Expenditures:

In Q3 2024, MAPS billed \$25,949.98 for direct administrative support of the VMR program for administrative information systems and administrative personnel and \$54,079.38 for indirect administrative expenses as per the updated budget. MAPS billed \$33,509.92 in project personnel expenses and \$49,306.50 for VMR contracted services, for a total of \$82,816.42 for VMR program expenses. Total expenditure to date equals 12.9% of the total contract value.

Due to a reduction in staff in September 2024, administrative project responsibilities were internally redistributed among the remaining staff members. In accordance with this transition, funds that were previously budgeted to specific staff members have been redistributed to the remaining staff who have been reassigned the relevant responsibilities as follows:

- The responsibilities previously fulfilled by our former VP of Finance and Philanthropy, Erin Tasman, have been reassigned to our Director of Development, Lindsay Robinson, our Director of Finance and Human Resources, Steven Huang, and our Director of Communications and Strategy, Betty Aldworth. Accordingly, the remaining budget associated with these responsibilities has been reallocated to these staff members as noted in the budgeted amounts in our Budget-to-Actual report enclosed here.
- The responsibilities previously fulfilled by our former Deputy Director, Fede Menepace, have been reassigned to our Executive Director, Kris Lotlikar, and our Director of Policy & Advocacy, Ismail Lourido. Accordingly, the remaining budget associated with these responsibilities has been reallocated to these staff members.

- The responsibilities previously fulfilled by the former Accounting Manager, Ryan Barnes, have been reallocated to our People Operations Manager, Amanda Ball, given her responsibility for supporting accurate reporting of personnel expense data. The remaining budget associated with these responsibilities has been reassigned to the People Operations Manager accordingly.
- The responsibilities previously fulfilled by our former VP of People and Operations, Jennifer Ellis, have been reassigned to the Director of Finance and Human Resources, Steven Huang, and the remaining budget has been reallocated accordingly.
- The remaining budget for our former Senior Accountant, Emily Williams, has been reallocated to our Communications Officer, Grace Cepe. While the Accounting responsibilities will be fulfilled by our Director of Finance and Human Resources and our People Operations Manager, it has become necessary to allocate funds to public communications for the grant and research program. Communications Officer Grace Cepe is leading our effort to communicate publicly about the successes of the VMR program to educate the public on current policy and research opportunities and to generate public awareness and support for research among veterans.
- The responsibilities previously fulfilled by our former General Counsel, Ray Allen, have been reassigned to Outside Legal Counsel, Allyson Deraps, and the remaining budget has been reallocated accordingly.

These changes are reflected in the Personnel Totals through Q3 2024 report. Personnel who were newly reallocated budgetary funds due to this redistribution of responsibilities are noted in yellow. Former personnel who left MAPS as a result of the reorganization are noted in orange.

The following corrections to personnel expenses were also made in this report and the associated documentation is provided.

- The Q1 2023 and Q2 2023 expenses (totaling \$1,217.86) for Ray Allen's in-house legal counsel were not previously reported in the quarterly reports, but were included as costs in the budget amendment, and have therefore been included in this quarterly report for accuracy and consistency.
- The salary and employment taxes for Project Director, Allison Coker, were erroneously underreported in Q2 2024 and have been corrected in this report. The cost of Allison Coker's time in Q2 2024 was \$19,678.76, rather than the previously reported figure of \$7,198.19.
- The 2023 employment taxes expense for Project Director, Allison Coker, totaling \$2,390.97, was erroneously excluded from the total VMR personnel expenditure figure in the Q2 2024 report, despite its inclusion in previous reports and the budget amendment. This expense was therefore restored in the current report.
- The 2023 fringe expense for Project Manager, McKenna Leighton, totaling \$1,262.15, was erroneously excluded from the total VMR personnel expenditure figure in Q2 2024 report, despite its inclusion in previous reports and the budget amendment. This expense was therefore restored in the current report.