



MJP2 Quarterly Progress Report – Q1 2026
Reporting Period: Jan 1, 2026 – March 31, 2026

April 15, 2026

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

MAPS has performed approximately 25% of the work initially proposed in the statement of work.

2. Program Progress Updates:

Study Start Up:

During this reporting period, study start-up activities continued to progress steadily across regulatory, site, and operational workstreams with cross-functional coordinated support from the Contract Research Organization (CRO).

Compliance and Oversight:

During Q1 2026 we finalized an updated protocol amendment to better support site startup (see Regulatory). We identified a Chemistry, Manufacturing, and Controls (CMC) lead to support MAPS' oversight of Investigational Medicinal Product (IMP) related compliance, and continued planning IMP strategy to address the FDA commitments for stability data.

The study CRO continued preparations for study startup, including drafting a Data Monitoring Committee (DMC) Charter and Manual of Procedures (MOP) for Sponsor review. These key documents are undergoing Sponsor review and moving towards finalization. The CRO also collaborated with the Data Management vendor to support the development of the Electronic Case Report Forms (eCRFs) as part of the ongoing design and build of the centrally hosted Electronic Data Capture (EDC) system that will be used across all study sites.

Site Selection and Development:

During this reporting period, MAPS continued significant effort and work on site-level engagement, recruitment, and contracting. We continued site assessment and qualification activities, making significant progress with both VA (n=3) and academic/private sites (n=4), presenting and negotiating site-level budgets and Clinical Trial Agreements in parallel to streamline study timelines, including collaborating on a Cooperative Research and Development Agreement (CRADA) agreement process with the Orlando VA. We further expanded outreach and engagement efforts to identify a Michigan-based study site, and while initial discussions seemed promising, no site has been recruited at the time of this report.

Investigational Product:

During this reporting period, MAPS received formal NIDA approval for the study supply of placebo Cannabis. The NIDA placebo Cannabis will next be released to Aqualitas, the licensed cannabis producer in Canada that is providing the active cannabis for the study. Aqualitas will develop the study-matched active and placebo pre-roll products in the final study packaging for

final drug product stability assessment as agreed and committed to FDA.

MAPS continued planning with Aqualitas on manufacturing readiness, validation requirements, and stability planning for the IMP, including finalization of the associated timepoints and reserve sample approach.

During this period, MAPS additionally began reviewing qualified vendors to act as licensed pharmaceutical distributor to receive, store, and distribute blinded study drug (active and placebo) to sites under DEA Schedule I regulations. The distributor will act as the Importer of Record for Cannabis supply, and handle additional tasks including IMP labelling and randomization, secondary packaging for randomization ease at clinical sites, distribution of IMP to sites, and reverse distribution (e.g. collection) and destruction of remaining IMP at the end of the study. To support these efforts, MAPS is enlisted the consultation of a former DEA agent who is providing advisory and technical assistance with Schedule 1 licensing for the study sites, and for import/export logistics for the IMP.

Regulatory:

During this reporting period, MAPS submitted the 2025 Cannabis Data Safety Update Report (DSUR) to the FDA. The DSUR serves as the FDA required Annual Report, which provides an annual safety update on the IND and conduct of studies in its scope in accordance with FDA expectations for ongoing clinical investigations. The 2025 DSUR report reflected the startup period and reported no new safety findings.

Additionally, MAPS drafted the MJP2 Protocol Amendment 4, Version 1 (A4V1) and submitted this amendment to the FDA for review. This amendment was developed to further support study startup by completing administrative and operational refinements in advance of study initiation. Amendment 4, Version 1 updates the previously cleared smoking-only protocol (A3V1) and removes duplicative procedures, updates screening and secondary outcome measures to reduce participant burden, and incorporates administrative updates for clarity and consistency.

MAPS remains committed to addressing the FDA's remaining clinical hold comments related to the vaporization device and intends to submit a future amendment and hold response to propose reintroduction of this administration method. Until such time, all study-related conduct will continue to be conducted solely under FDA-cleared smoking-only protocol version, and study startup will proceed with the currently cleared protocol to ensure that efforts to include this additional administration, while important for the intended study data, do not impact timelines for the study initiation.

3. Description of New Problems and Delays:

Considering the logistical and regulatory complications associated with importing IMP from Canada, and the subsequent randomization and distribution to clinical sites, we are assessing potential vendors to act as licensed pharmaceutical distributor to streamline this activity. This assessment has includes competitive bidding process, vendor negotiation, and vendor site audits. To minimize study delays, we are conducting these assessments and processes in parallel with other key start-up activities.

4. Statement regarding any deviation from SOW:

Personnel Modifications:

Matt Clark has been promoted to Associate Director of Finance and is assuming the role of MAPS' Finance lead as well as primary grant administrator for this grant – expanding his responsibilities on the project.

Other Deviations:

None

5. Quarterly Financial Expenditures:

See attached Financial Report.

6. Corrections:

None