



MJP2 Quarterly Progress Report – Q4 2025
Reporting Period: Oct 1, 2025 – December 31, 2025

January 15, 2026

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

MAPS has performed approximately 20% 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 the added cross-functional coordinated support from the CRO.

Compliance and Oversight:

The protocol and informed consent form (ICF) have been reviewed and approved by Advarra IRB. Further development of the MAPS Quality Management System was made, including the initial drafting of internal SOPs to address internal study oversight procedures.

MAPS contracted Dr. Michael Mithoefer to serve as the Sponsor's Medical Oversight Lead for the trial based on his extensive and directly relevant and unique experience in overseeing safety and pharmacovigilance for MJP1, a previous study of cannabis and PTSD. Dr. Mithoefer began reviewing the CRO-drafted Data Safety Monitoring Plan (DSMP).

The Manual of Operations and Procedures (MOP) is in its final draft stage and is expected to be finalized in Q1 2026. Lastly, identification of Data and Safety Monitoring Committee (DSMC) members is underway to support ongoing safety oversight.

Site Selection:

MAPS identified a number of potential study sites, with the goal of activating at least six sites at both academic and VA centers across the US. The CRO supported initiating formal feasibility assessments at nine potential sites. Seven of these potential sites have completed feasibility packages/pre-study questionnaires. Of which, four underwent Site Qualification Visits. We have approached a number of Michigan-based sites and are currently optimistic about partnering with a potential site at MSU.

To support site contracting, we collaborated with the CRO to develop a site budget and a Clinical Trial Agreement (CTA) template to negotiate and execute with each site. VA site contracting activities are also in progress, with a focus on finalizing a Cooperative Research and Development Agreement (CRADA), which is being led by the Orlando VA. We plan to finalize the contracting (CTAs or CRADA) with the study states during Q1 2026.

Investigational Product:

During this period, MAPS' QA lead conducted a site audit of Aqualitas, the producer of the active Investigational product. This audit was successfully passed. MAPS also continued to engage with NIDA, the producer of the placebo product, with subsequent plans to move forward with a quality audit of this supplier as well in Q1 2026.

Other Vendor Engagement

Engagement with the study's contracted Independent Rater vendor resulted in improvements to the plan for study measures and associated processes for independent rater assessments during screening and over the course of the study. This modification has reduced anticipated costs for the independent rater vendor for the study while also reducing participant burden and improving the balance of assessments.

Regulatory:

During this reporting period, we developed the updated annual Development Safety Update Report, which was submitted to the FDA at the start of Q1 2026.

We developed a protocol amendment to incorporate updates developed in collaboration with the cross-functional teams, including the Independent Rater Vendor and CRO. These updates will streamline study procedures, and measures will be updated to be more accessible and reduce participant burden. This amendment will be finalized and submitted to FDA in Q1 2026 and is intended to be the protocol version provided to sites to initiate the trial.

3. Description of Problems and Delays:

None

4. Statement regarding any deviation from SOW:

Personnel Modifications:

None

Other Deviations:

MAPS contracted with Dr. Michael Mithoefer for Medical Oversight Lead services.

5. Quarterly Financial Expenditures:

See attached Financial Report.

6. Corrections:

None