



MJP2 Quarterly Progress Report – Q2 2025

July 15, 2025

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

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

2. Program Progress Updates:

Following the successful removal of the FDA's long-standing clinical hold on this trial (as reported in the last reporting period), MAPS continued efforts to initiate study start-up after this long and unanticipated delay.

Study Start Up:

In Q4 2024, MAPS began study start-up activities with the Contract Research Organization (CRO). As described in MAPS' initial application and as previously reported, much of the overall project and program management responsibilities were previously delegated to MAPS' former subsidiary, Lykos Therapeutics (formerly MAPS Public Benefit Corporation), and to a CRO. As previously agreed to in the contract amendment, responsibilities previously assigned to Lykos Therapeutics will need to be reassigned to a CRO in a new contract.

CRO Contracting:

In Q1 2025, MAPS engaged in budget planning meetings with the previously selected CRO to review and update the budget within the current scope of the study. Given the updated Sponsor structure and timelines, in order to ensure that the CRO was the most qualified and cost-effective vendor to proceed with the study, MAPS also sought additional bids from nine total CROs, resulting in four budgeted proposals.

In Q2 2025, MAPS identified a lead CRO candidate and conducted contract and budget negotiations to ensure proper management of study responsibilities and funds for the updated study timeline and protocol.

Compliance and Oversight:

To ensure proper quality and compliance in delegation activities, MAPS conducted a search for an experienced Quality Assurance (QA) specialist to develop an internal Quality Management System (QMS) including a vendor qualification process. Three QA specialists were interviewed and provided bids, and a QA specialist was selected and contracted based on qualifications and budget. Currently, MAPS QA specialist is overseeing the vendor qualifications process for the lead CRO candidate, including conducting an internal Sponsor audit in Q2 2025. Following a completed audit certificate, vendor qualification, and final contract negotiations, MAPS anticipates signing with this new CRO in early Q3 2025.

MAPS has also begun identifying appropriately qualified Subject Matter Expert (SME)s to serve as a Medical Oversight and Pharmacovigilance lead for the study, a role which will likely be activated

in Q3. Along with our internal research team, these two SME additions to the MJP2 team will ensure effective and compliant oversight of the delegated study activities.

Site Selection:

During this reporting period, MAPS initiated discussions with new potential study sites to gauge interest and qualifications. An estimated total of six study sites are anticipated to support recruitment timelines. Once a CRO is contracted, the CRO will conduct site qualification assessments (planned for Q3 2025) followed by Site Initiation Visits (SIVs) (planned for Q4 2025).

Investigational Product:

MAPS has continued discussions with the two vendors for the provision of Investigational Products (IP) for this study. Additionally, during this reporting period, MAPS initiated discussions with a potential shipper for the IP to ensure that all state, federal, and international regulations of importing and exporting controlled substances will be met.

Regulatory:

MAPS has continued work with the FDA to remove the continued partial hold on the use of the vaporization devices by study participants. MAPS believes that providing participants the option of inhaling cannabis through either smoking or vaporization is important to reflect and assess “real world” patterns of use. MAPS Regulatory Lead has worked with the vaporizer vendor to provide the available device data to the FDA in an effort to resolve the partial clinical hold on devices. On July 7, 2025, MAPS submitted a Complete Response to the FDA responding to these outstanding hold issues, including the provision of the available device data.

If this response is successful, vaporization will be added as an optional administration method in the protocol. As this addition can take place at any time within the current study design, this effort will not otherwise impede the study start-up efforts. If it is not cleared, the study protocol may proceed in its current form, with smoking only as an administration method.

3. Description of Problems and Delays:

As the study is now cleared by FDA for smoked cannabis, the regulatory delay has now been addressed and the necessary study start-up steps are ongoing as described in this report. Additionally, MAPS will continue to assess the required personnel needed to ensure appropriate oversight as study development plans continue with external vendors.

4. Statement regarding any deviation from SOW:

Personnel Modifications:

As reported in the report submitted April 15th, MAPS has hired Philippe Lucas, PhD, as Director, Research & Safe Access. Dr. Lucas began filling the role of Clinical Program Manager for the MJP2 study in February of 2025. Dr. Lucas' Q1 compensation was not available for reporting at the time of the Q1 financial report, but is now reported in full, in addition to his Q2 compensation, in the current report.

Other Deviations:

During this reporting period, Brandon Phillips was contracted to provide Quality Assurance services for the study. Mr. Phillips was selected after completing a competitive bidding process. During this quarter, the services Brandon provided supported the regulatory affairs function of the study, developing the necessary QA/QMS processes and systems to support regulatory compliance. Therefore, MAPS has billed his services to the Regulatory Affairs Contracted Services budget line item.

5. Quarterly Financial Expenditures:

In Q2 2025, MAPS billed \$33,896.04 for direct administrative supplies and personnel of the VMR program, and \$54,079.38 for indirect administrative expenses. MAPS billed \$68,582.32 in program personnel expenses and \$8401.67 for VMR contracted services. Total expenditure to date equals 16% of the total contract value.