



MJP2 Quarterly Progress Report – Q3 2025
Reporting Period: July 1, 2025 – September 30, 2025

October 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:

CRO Contracting:

In Q3, MAPS and our contracted Quality Assurance (QA) specialist conducted and concluded a vendor qualification audit of Changemark, the lead Contract Research Organization (CRO) candidate for the MJP2 research project. We identified Changemark during an open re-bidding process for CRO services where we assessed nine CROs. After completing the qualification audit, MAPS entered into a contract arrangement with Changemark, and began reassigning CRO responsibilities from Alira Health to Changemark.

Study Start Up:

During this reporting period, MAPS and Changemark conducted onboarding and alignment activities involving various internal team members and external collaborators and contractors; identified and began to assess study sites; submitted the MJP2 protocol for IRB review; and met with Investigational Drug producers in Canada and the US.

Compliance and Oversight:

The MJP2 protocol was submitted to Advarra, the ethics review organization selected as the central IRB for the study. Additionally, in order to ensure proper quality and compliance activities for the study, work was conducted on the MAPS Quality Management System by MAPS, our QA contractor, and Changemark. Work included the drafting of a delegation of authority log, additional edits to the MAPS internal SOPs, and seeking and receiving sole source selection permission from VMR for the contracting of a Medical Oversight lead for the study. Finally, MAPS QA scheduled a site audit for November to re-qualify the Canadian licensed cannabis producer and we have reached out to NIDA/NIH to proceed with a quality audit of their processes and investigational product.

Site Selection:

MAPS has identified and contacted various potential clinical sites at both academic and VA centers across the US. Changemark has begun site assessment activities for seven potential sites, distributing site assessment questionnaires to better understand the qualification. MAPS is placing a priority on identifying and contracting with Michigan-based sites, however it is proving difficult. Unfortunately, Detroit and Battle Creek VA sites have declined participation in the study, but we are continuing to explore and engage with potential sites in Lansing and Traverse City.

Investigational Product:

MAPS and Changemark engaged with Aqualitas, the licensed, Canadian producer of the Investigational Drug, during this reporting period to discuss and agree to timelines, packaging, shipping and other study responsibilities and expectations. Additionally, during this reporting period MAPS tasked Changemark with initiating the drug supply request process with NIDA/NIH in order to get the placebo exported to Canada for final packaging into pre-rolls.

Regulatory:

During this reporting period, MAPS continued to 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. The protocol is currently cleared by FDA to proceed for smoking only, and regulatory efforts to add vaporization as an optional administration method in a protocol amendment will not impact other study start-up activities. If this effort is successful, this amendment could be implemented at any time point in the study with little to no impact on study timelines.

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.

On August 5, 2025, FDA issued a partial clinical hold on the new amendment to reintroduce vaporization, indicating that the information provided is not adequate to support the safety of the proposed device for the exposure period in the study protocol. MAPS’ Regulatory Lead is working with FDA to evaluate additional strategies to better align the safety data and the exposure period in the protocol to allow for the potential inclusion of an optional use of the vaporization device. An updated protocol amendment and hold response will be submitted to FDA in Q4 2025 for FDA to consider this proposal.

3. Description of Problems and Delays:

As study start up activities accelerate, we have modest concerns that the recent government shut down may impact typical timelines for supply and regulatory activities. Additionally, despite putting tremendous time and energy into the recruitment of potential clinical sites in Michigan and beyond - both VA and academic institutions - we do not yet have the desired number of clinical site agreements in place.

4. Statement regarding any deviation from SOW:

Personnel Modifications:

None

Other Deviations:

None

5. Quarterly Financial Expenditures:

In Q3 2025, MAPS billed \$81,495.26 for indirect administrative expenses; and direct administrative supplies and personnel of the VMR program. MAPS billed \$320,896.06 in direct program expenses. Total expenditure to date equals 19% of the total contract value.

6. Corrections:

In the submitted Q2 2025 financial report, we incorrectly reported that the Total Expense to Date of "VMR Contractual Services – Regulatory Affairs Contract Services" line item was \$213,697.91, rather than the correct total of \$214,260.41. An updated Q2 Financial Report has also been provided along with this Q3 report.