

# MEETING MINUTES

## Consortium for Medical Marijuana Clinical Outcomes Research:

### BOARD MEETING

**Tuesday, Oct 15th, 2024 at 12:30 pm**

*Remote Connection via Zoom*

#### **Board Members Present:**

Max Orezzaoli, Chair  
William Anderson  
Martha Rosenthal  
Dinender Singla  
Jacqueline Sagen  
Christopher McCurdy  
Eric Holmes

Md Mahmudul Hasan  
Jeevan Jyot  
Allison Veliz  
Alicia Koshevoy

#### **Team Members Present:**

Almut Winterstein  
Amie Goodin  
Yan Wang

#### **Opening Remarks: Welcome to the Board Members**

Dr. Max Orezzaoli, the new chair of the Consortium board, called the meeting open at 12:36 PM EST and welcomed the board members.

#### **Overview of Consortium Research Plan 2024-2025**

Dr. Winterstein presented the Consortium Research Plan for 2024-2025 and highlighted achievements under each of the five consortium pillars. The **Grants Program**, has awarded 54 awards totaling more than \$3.6 million to date, the **Clinical Core** supports prospective studies including randomized controlled trials (RCTs), **Outreach** involves organizing CCORC, the annual conference, a quarterly newsletter, website, and conference exhibits, the **Evidence core** which provides evidence reviews and the evidence in context series and **MEMORY** which involves a data repository capturing medical marijuana (MMJ) purchases, disease history, and clinical outcomes for 1.2 million patients available for Consortium researchers. Dr. Winterstein shared that data collection for Medical Marijuana and Me (M<sup>3</sup>), which includes a cross-sectional sample of 632 patients, and a longitudinal cohort of 602 patients has been completed, with de-identified datasets finalized and ready for user access. Two manuscripts on M<sup>3</sup> have been published and several in preparation. Dr. Winterstein provided updates on the Clinical Core activities, which include consultations to Consortium-affiliated institutions on clinical trial designs and pre-IND evaluations by Dr. Robert Cook and Sheila Austin, to assist in protocol development for FDA approval. Additionally, Dr. Winterstein provided updates on the CARMMA (Connect and Advance Research for Medical Marijuana Analysis) database, which is now publicly available for viewing and collaborating. The Outreach core is continuing its Consortium Researcher Spotlight series, participating in conferences, utilizing the Consortium website, planning annual conferences (CCORC), and distributing MEDICAMENT, the quarterly newsletter disseminated to over 1,600 individuals. Lastly, Dr. Winterstein introduced Consortium Info Sheets which were requested by the Department of Health to provide objective evidence-based information on marijuana benefit and risk for patients and consumers. These info sheets are disseminated through hosting resources online and making physical copies available.

Dr. Winterstein highlighted that the Consortium was invited by the FDA to collaborate on the rescheduling of cannabis and contributed to the FDA's report on cannabis risk/benefit that informed schedule change recommendations. Dr. Winterstein mentioned that federal scheduling change is likely, but the process involves several more steps, and it may lead to new challenges surrounding regulation. Dr. Orezza congratulated Dr. Winterstein, Dr. Goodin, and the rest of the team who worked on the report to the FDA. Dr. Winterstein also addressed Amendment 3 which has been proposed to allow for recreational marijuana use in the state of Florida. Potential implications for the Consortium include MEMORY being impacted due to the registry currently only containing MMJ patients. Dr. Sagen raised concerns about the disconnect between federal and state marijuana policies and the possibility of research processes being complicated. The implications for re-scheduling are significant, potentially reducing regulatory barriers for obtaining, administering, and monitoring cannabis within clinical and translational research.

Dr. Winterstein provided a summary of CCORC 2024, which included 110 total registrants and 57 oral and poster presentations. The feedback survey was positive, mentioning that the conference was informative to research and practice, presentations were free of commercial bias, and the presentations were engaging. For next year, there was a desire for more clinical guidelines or expert opinion for cannabis dosing and clinical recommendations or guidance for patients using marijuana.

For next year's conference, Dr. Orezza proposed the dates of either May 15<sup>th</sup>-16<sup>th</sup> or May 22<sup>nd</sup>-23<sup>rd</sup>, 2025 to be voted on via email once confirmed with the events planner on dates they can accommodate. The board members agreed with the preference of these dates. Dr. Dinender Singla raised the possibility of changing the venue for CCORC, suggesting that it could be held at a different location in the future. Dr. Winterstein responded that while considering other locations is a possibility, Orlando's Lake Nona location seems optimal due to its centrality and the availability of UF resources. Dr. Singla enquired about available budget for the conference, and Dr. Winterstein clarified that in addition to the venue it includes student scholarships for conference attendance, awards, speaker honoraria, food, travel expenses, and hotels. Dr. Winterstein and Dr. Orezza suggested leaving the venue as it is for the upcoming year but agreed to discuss the possibility of hosting CCORC at a different city and venue in more detail at the next board meeting.

#### [Consortium's Funding Update & Budget Proposal FY25](#)

Dr. Winterstein provided an overview of the Consortium's research plan for fiscal year 2025. Presently, no massive changes will be made to the Consortium's structure. The Consortium will provide required CME for physicians authorized to prescribe MMJ, in collaboration with the Department of Health, OMMU, and FMA. Additionally, physician info sheets will be developed focusing on MMJ use with nausea as well as anorexia within the population of patients with HIV/AIDS. M<sup>3</sup> will continue to be analyzed and move forward into Phase II to focus on high-priority conditions that were under-represented in Phase I. This will focus on developing recruitment infrastructure for clinical centers and dispensaries, and focusing on conditions for which pilot data would be helpful to Consortium researchers such as cancer, pain in special populations (e.g., hemodialysis patients), neurological disorders, or priority populations defined by the NASEM 2024 report (e.g., pregnant women). MEMORY studies will focus on driving safety, opioid use, and MMJ use in children and during pregnancy. Additionally, Dr. Winterstein explained that the Research Priorities (RP) for the Grants Program have been updated and expanded based on the National Academies report.

Dr. Sagen expressed concern about how changing laws and regulations could affect research outcomes due to patients being able to freely access marijuana and suggested modifying RP number five on public health outcomes to include a research component. Dr. Orezza put forth a motion to approve the RP changes with the modified component on RP number five to add in Dr. Sagen's suggestion to include research considerations in relation to the changing landscape of cannabis laws and regulations. The motion was approved with no oppositions and no board members abstained from voting. RP number five will be modified with the recommendation from Dr. Sagen

and distributed to the board members via email for final approval. Additionally, Dr. Winterstein mentioned that there will be a new rule added to the request for proposals to make awardees eligible to apply again one year after their previous grant has ended. This will allow for different researchers to have the opportunity to receive funding.

Dr. Winterstein mentioned that the funding awarded to the Consortium will remain the same at \$1,500,000 and shared the budget allocation for FY25.

#### [Comments and Vote on Approval for FY25 Budget](#)

Dr. Orezzoli proposed a motion to approve the FY25 budget. The board approved the budget as presented. No board member opposed the decision, and no board members abstained from voting.

#### [Public Comments](#)

There were no public remarks.

#### [Closing Remarks](#)

Dr. Orezzoli thanked Dr. Winterstein and the team, and all members agreed to maintain communication via email for scheduling the next board meeting in 2025.

#### [Adjournment](#)

Dr. Orezzoli adjourned the meeting at 1:34 PM EST.