

MEETING MINUTES

Consortium for Medical Marijuana Clinical Outcomes Research:

BOARD MEETING

May 19th, 2023 at 12:00 P.M. (EST)

Live and Remote Connection via Zoom

Attendees (in-person):

Todd Schimpf
Peter Holland
Charles Weatherford
Jacqueline Sagen
William Anderson
Max Orezza
Dinender Singla
Roger Fillingim
Almut Winterstein
Jeevan Jyot
Robert Cook
Yan Wang
Amie Goodin

Ruba Sajdeya
Sebastian Jugl
Sam McKee
Alicia Koshevoy
Nele Melcher
Eva Spin
Laura Springer
Lena Froehlich
Diana Kretschmer

Virtual Attendees:

Eric Holmes
Martha Rosenthal
Jeffrey Block

Welcome:

Dr. William Anderson welcomed all attendees to the board meeting and everyone introduced themselves.

OMMU: Collaborating with the Consortium

OMMU communications manager Todd Schimpf representing Chris Kimball, OMMU Director, introduced the OMMU as the governing body for the medical marijuana (MMJ) use program in Florida. OMMU oversees the patients, caregivers, part of the physicians, the mmj treatment centers (MMTCs), and certified testing laboratories. The MMJ user registry (MMUR) ties together physicians with MMTC and patients. Mr. Schimpf shared that the new OMMU Director plans on outreach events through the year, to meet with leaders from law enforcement, patient groups, and physicians to receive feedback on the program. Mr. Schimpf revealed that the biggest questions asked by physicians are about dosing, which is something he hopes the Consortium can help answer. Patients, prescribing physicians and MMTCs need education to fill information gaps to enable better decision making. OMMU aims to inform the various physician groups about the Consortium's research and the importance of inputting better data in the available fields in the MMUR. Mr. Schimpf invited thoughts on how OMMU could help strengthen the relationship with the Consortium.

Dr. Almut Winterstein mentioned meeting with Chris Kimball at the Healthcare subcommittee hearing in February and having discussed making research information available to OMMU, providers and patients. Dr. Amie Goodin is leading an FDA project, that will synthesize evidence on mmj use and in addition to publishing for the scientific community, this data and information generated, will be made available in an easily digestible form to the community. The Consortium has a DUA agreement established with OMMU which allows receiving regular data updates. Meetings with OMMU are planned every 3 months to allow feedback on the data. Dr. Winterstein also reiterated the importance of dosing and the political concerns of setting dosing limits. In this regard, the Consortium has connected Chris Kimball with Dr. Shanna Babalonis, a scientist with experience in testing cannabis at various doses within clinical trials, and who was also a Keynote speaker at the recently concluded CCORC conference.

Dr. Winterstein invited additional thoughts from Mr. Schimpf and the board. Mr. Schimpf mentioned that based on received call centers queries, patients are relying on medical treatment center staff for product selection and treatment for their medical conditions, rather than their own medical providers. This appears to be based off the California budtender model where the person actually recommending a product has no degree/formal training and thus more education on mmj is definitely needed for them and patients.

Dr. Robert Cook stated that the clinical core would like to push for clinical trials that use products in collaboration with dispensaries. After lawyer consultations and in a situation where there are any legal issues related to labeling, possession or getting an outside lab testing done, Dr. Cook enquired if perhaps OMMU could help with a rule change/exemption that would allow bonafide research to be conducted. Mr. Schimpf stated that during the Dr. Cook's presentation sharing M3 data, some physicians in the audience wanted chronic pain to be added to the Florida list of qualifying conditions. That however is a statute change and OMMU cannot make those changes. OMMU can write a rule to add clarity but cannot amend an existing statute or lobby for a change. The statute should have made allowances for state universities to conduct research when it was established similar to the data access allowances. Dr. Winterstein stated that the major issues are still with the FDA IND process, for administration of MMJ in clinical trial conditions and other federal regulations surrounding MMJ.

Dr. Dinender Singla asked if the Consortium could publish annual guidelines from existing dispensary data. He suggested participation by member universities to work with local dispensaries and collate data to compare the products used, the ones that provided benefit, more side effects in one medication versus another, kinds of cannabinoids used, dose over a one/two-year survey-based study etc. and publish this data in a national journal. This would be a way to gather and give back to the community. Mr. Schimpf appreciated all inputs and encouraged discussion with Chris Kimball at future meetings. Dr. Orrezzoli enquired about OMMU's protocol regarding the dissemination of research data and suggested creating a mobile application to make data easily accessible. Mr. Schimpf explained that OMMU primarily utilizes the registry, website and email (no phone calls), for communication with patients and providers, and mentioned that utilizing a mobile application may cause security concerns with patient data.

Dr. Block (public attendee) commented upon the importance of studying clinical correlations to determine which subset of patients with different qualifying conditions should seek treatment and at which doses.

CCORC 2023 Post Hoc

Dr. Goodin provided an overview of CCORC 2023, highlighting 134 total registrants, a third being students and 17 online attendees. There was a doubling in the number of oral presentations, a 30-40% increase in research abstracts that were selected after peer review. Symposia proposals were a new addition to the program structure. CE credits made available this year as well, attracted more clinical audience members. Feedback survey will be shared and is greatly important to the success of next year's conference. The Medical Cannabis and Cannabinoids Journal will publish this year's conference abstracts.

Dr. Winterstein asked for feedback from the Board members regarding the 2023 conference. Dr. Orrezzoli stated that he was impressed with this year's conference and the noticeable growth over the past three years. Dr. Sagen appreciated the broad perspectives of attendees and their questions for speakers, as well as the poster sessions. Dr. Holland stated the conference is important and it serves as a catalyst for much needed mmj research. Drs. Orrezzoli and Winterstein expressed appreciation for the contributions of the organizing and planning committee. Dr. Rosenthal mentioned that abstracts could not be accessed online, so online participants could only watch the keynote presentations. Dr. Winterstein confirmed that this was correct and this hybrid format was strategically intended to promote in-person attendance rather than providing a full virtual option to the attendees.

Consortium Progress Updates and Upcoming Activities

Dr. Winterstein shared the growing Consortium outputs included in the Annual Report submitted to the Governor and legislative members. Dr. Winterstein reported presenting to the FL House Subcommittee on February 15th, which gathered positive feedback. Annual highlights and key initiatives were highlighted and additional funding for the following years was requested. A fall meeting for planning the financial strategy for requesting an increase in budget will be planned. Dr. Anderson agreed to a continuing annual funding increase and pointed that an increase in Consortium funding benefits the entire SUS and government relations at each member institution can be helpful.

Dr. Winterstein provided updates on the five Consortium pillars. The Grants program is gearing up to finalize the awards for the fifth cycle in early July. Towards establishing MEMORY, the OMMU DUA is established, data received, with monthly updates. The DUA with CMS and for Vitals data is finalized and the last IRB from DoH is currently under review. Data curation is ongoing with plans to link MMUR data to claims data and Vitals data. Dr. Winterstein stated the plan to link this data with M3 cohort, EHR data, car crash data. Interest for linkages to cancer registry from Moffitt and University of Miami was received and we will look into. For the M3 patients, recruitment is completed and database has been locked to start data curation. Regulatory process for data access by Consortium researchers has been established.

Dr. Winterstein highlighted the ongoing Consortium and FDA collaboration to synthesize evidence on clinical risk benefit in order to review marijuana's current Schedule I classification status. Dr. Goodin leads this Federal level grant and the comprehensive assessment conducted will result in a final report by June, similar to NASEM report from 2017 and lend desirable spotlight on the Consortium. The Evidence core continues to publish new articles in its official journal and these are available on the Consortium website. Outreach activities include the quarterly Newsletter MEDICAMENT and research spotlight series. Dr. Winterstein asked for suggestions for researchers to be featured in the spotlight video series, which helps illustrate to consumers and providers how research is conducted.

Dr. Winterstein invited board discussion on a fellowship opportunity brought forth by UF's Development office, sponsored by Dewar nursery (Sanctuary) and emphasized the need for the Consortium's stance to be differential. Dr. Anderson responded that the fellowship and scholarship can be accepted by UF, but the Consortium should not accept or endorse "gifts." If there were gifts intended directly for the Consortium, he recommended that UF's general counsel be consulted to ensure appropriate stipulations are in place that prevent any conflict of interest. Dr. Singla pointed out that there may appear to be a conflict of interest with the Consortium if the Consortium name is used for product advertising, distribution or by association. Dr. Orrezoli stated that funding from private sources is not prohibited according to statute, and suggests the Consortium apply to grants at foundations for additional funding opportunities. Dr. Anderson emphasized the need to "report not endorse" and redirect the interest to UF directly and pull in UF counsel to ensure appropriateness. Dr. Winterstein thanked the board for their guidance and stated that after suggested discussions the proposal would be brought back to board for approval.

Public Comments

The Chair invited comments from the public and Dr. Block asked if the Consortium has been involved with human and plant genomics research involving mmj since UM has a vested interest. Winterstein responded that the Consortium is not involved in genomics research.

Closing Remarks

Dr. Anderson thanked all in attendance and the next board meeting will be scheduled in June, to discuss the grants to be funded for the 2023 grants program.

Adjournment

Dr. Anderson adjourned the meeting at 1:05 PM.