

California Precision Medicine Advisory Council Meeting Summary, December 12, 2023 1400 Tenth Street, Sacramento, CA 95814 (Virtual)

Opening Remarks from the Chair and Vice Chair

Clara Lajonchere, PhD, Chair

- Federal funding trends are indicative of the larger picture of health innovation transformation: More players are engaging in the ecosystem; the federal government seems to be investing as a result of learnings from the pandemic; and paradigms are shifting with new approaches making their way entirely through the pipeline, as we've seen with the first-ever FDA-approved CRISPR therapies.
- Our state-level CIAPM experiment will turn nine years old soon; it feels simultaneously established and still brand new. How far we've come, displayed in stark contrast with the Depression RFP's months-long listening sessions across the state, the program's first-ever RFI, and cross-agency partnerships with the California Surgeon General and Mental Health Commission that led to the most thoroughly crafted RFP.
- Though research isn't known for its swiftness, we're seeing examples every month of how the enterprise itself is changing, and it's hopeful to see California continuing to invest in the staff and programming that help keep us at the leading edge.

Keith Yamamoto, PhD, Vice Chair

- In addition to CIRM (California Institute for Regenerative Medicine), CIAPM is one of two major, distinctive programs that have a flagship role in state-funded stem cell and gene and cell therapy research. CIRM is undergoing a change of leadership. One common goal between CIRM and CIAPM is to engage in data sharing and developing a knowledge network.
- CIRM made a major commitment to focusing on neuropsychiatric disease via \$1.5 billion of funding, and this focus aligns closely with our focus on funding depression research. Due to these areas of overlap and opportunity for synergy, and the upcoming challenges of gaining support for science and technology and

biomedical research and health research at the federal level, the prospect of developing our relationship with CIRM is especially important.

• The role of CIAPM and the state's commitment to groundbreaking biomedical and health research and healthcare is not only deep, but also broader than ever before.

Updates from the Governor's Cabinet

Richard Figueroa, MBA, Deputy Cabinet Secretary

Budget Outlook

Administrative Business

- 1) Introducing new members of the CIAPM team
 - Hanna Butler-Struben (UC Davis; Graduate Intern)
 - Joanna Guan (UC Davis; Graduate Intern)
- 2) Previous Meeting Summary (Sept. 25, 2023)
 - Clara: Motion to approve the meeting summary
 - Keith: Second the motion

No oppositions, the motion passes

- 3) Proposed Amendments to the Bylaws
 - Flexibility to meet virtually (Article 3, Section 14)
 - Previously: "The Council should meet at least four times annually, in person; in-person meetings should be held in locations that allow stakeholders in different regions of the state to participate."
 - As amended: "The Council should meet at least four times annually, virtually or in person; meetings should be held in locations that allow stakeholders in different regions of the state to participate."

Kenneth Kim: Motion to approve amendment to the Bylaws, Article 3, Section 14 Debra Cooper: Second the motion

No oppositions, the motion passes

- Allow the option to increase the number of CalHHS seats from one to two (Article 2, Section 1)
 - Previously: "1. The Council should consist of the following members: a. The Surgeon General of California, ex officio, b. the Secretary, a Deputy Secretary, or an Assistant Secretary, of the Health and Human Services Agency, ex officio, c. Members invited by the Governor's Office of Planning and Research, d. One member recommended by the Senate Pro Tem and one member recommended by the Speaker of the Assembly"
 - As amended: "1. The Council should consist of the following members, up to 13 total: *a*. The Surgeon General of California, ex officio, *b*. One or two individuals with the following positions at the Health and Human

Services Agency: the Secretary, a Deputy Secretary, or an Assistant Secretary, ex officio, c. **Up to eight** members invited by the Governor's Office of Planning and Research, d. One member recommended by the Senate Pro Tem and one member recommended by the Speaker of the Assembly"

Keith Yamamoto: Motion to approve amendment to the Bylaws, Article 2, Section 1 Kenneth Kim: Second the motion

No oppositions, the motion passes

4) Introducing a new Council Member

- Dr. K Jones (Assistant Secretary, California Health and Human Services Agency)
- 5) Decision: in-person or virtual for our March meeting

Context: Nonessential State-funded travel has been paused, in consideration of the State budget.

Unanimous decision: Virtual meeting

Major Program Updates

- 1) Depression Research RFP
 - Selection Process Underway (\$9 million total)
 - o 60 letters of intent (across 25 institutions)
 - 41 concept proposals (across 22 institutions)
 - 10~15 expected finalists
 - 3~5 expected awardees
 - Timeline
 - Jan. 17, 2024: Concept Proposal Selection Meeting
 - Jan. 2024: Notification of Finalists
 - Feb. 15, 2024: Due Full Proposals
 - Mar. 2024: Awardees Announced
 - o Jun. 2024: Anticipated Project Start
 - 36 months: Duration of Projects
- 2) Representative Research Collaborative (RR)
 - Finalization of MOU with NIH
 - RR Gap Analysis in Process

CIAPM's Purpose & Vision

1) Enabling Statute (Gov § 65055):

• "By establishing [CIAPM], the state can help coordinate public, private, and nonprofit partners to advance this important intersection between science, research, and medicine, and to foster the creation of new technologies and therapies that can improve the health of Californians."

• "[CIAPM] will bring together state precision medicine leaders as well as complete projects that demonstrate the power and application of precision medicine to the people of the State of California."

2) Precision Medicine: An Action Plan for California (2018)

- Co-authored by several CIAPM council members
 - o Dr. Sakul, Dr. Yamamoto, Dr. Lajonchere, Dr. Keown, Ms. Duron
- Published policy recommendations that have been implemented to date:
 - Data in the context of precision medicine (The Gravity Project, DHCS Medi-Cal, CHHS Data Exchange Framework, HCAI All-Payer Claims Database)
 - California as partners in care and research (CHHS Data Exchange Framework, HCAI All-Payer Claims Database, Representative Research Collaborative, Equitable Consent Working Group)

3) Programmatic Efforts

- Primary
 - Research Funding: 18 Precision Medicine Projects thus far, over \$40M
 - Cancer, Adverse Childhood Experiences, Infectious Disease, Imaging Biomarkers for TBI, Cardiovascular Disease, Remote Sensing, Multiple Sclerosis, Rare Diseases, Precision Medicine Delivery, Cross-Sector Coordination, Outreach
 - Cross-sector coordination
 - Advisory Council, All-Teams Meetings, Representative Research Collaborative,
 - o Develop/highlight public resources
 - Precision Medicine Primer, Asset Inventory, Educational Resources, Asset Inventory, Events Calendar
 - Outreach
 - Reports (Annual, Evaluation, Action Plan), Legislative Briefings & Materials, Requests for Information, Webinars, Newsletter, Website, Social Media, Public Meetings, Seminars, Conference Participation, Exhibit Booths, Informational Interviews
- Secondary
 - Support fellow public agencies
 - Federal (informal): NIH All of Us, ARPA-H, BARDA
 - State: California Surgeon General, Governor's COVID-19 Testing Task Force, Governor's Office of Business & Economic Development, Department of Public Health, Health In All Policies Task Force
 - Graduate internships/fellowships: 19 Interns and Fellows to date
 - Often interns' first policy experience
 - 3-27 months in duration

- Remote with hybrid option
- Several alumni have launched careers in policy: CA Legislature, NIH, CA Association of Health Facilities, State of Oregon HHS

2024 Priorities Discussion

Prompts:

1) How can CIAPM leverage the cross-sector nationwide health innovation network developed for ARPA-H?

2) How can CIAPM better influence/guide other funding agencies (federal, philanthropic)?

3) Who is the relevant audience for research policy innovations?

4) In what ways can CIAPM serve Californians more effectively? (Higher Ed?

Health/research data management? An honest broker for industry?)

5) What does closer industry partnership or support look like?

6) What critical topics are emerging?

7) Should CIAPM consider additional partnerships?

Discussion Highlights:

- CIAPM spearheaded cross-sector partnerships in support of ARPA-H and BARDA. There may be opportunities to further be of service.
- With so much happening around other State agencies, like the Data Exchange Framework, CalAIM, and All-Payer Claims Database, among others, are there opportunities for Council Members to be engaged in those programs, as precision medicine experts?
- The depression RFP is currently a model that is receiving some attention from external entities, including the NIH. The thoroughly crafted RFP is a culmination of listening sessions across the state, the program's first-ever RFI, out-of-state informational interviews, and cross-agency partnerships. Is there a position statement that CIAPM could develop and publish to provide a framework for organizations that want insight on improving equity-centered research outcomes? Could our landscape analysis in the depression research ecosystem be utilized beyond our RFP effort, especially as a gap analysis of state and federal portfolios and funding opportunities?
- CIAPM's work should be better promoted, including through a more functional website, increased social media presence (including LinkedIn, where much professional exchange occurs), and possibly via promotional efforts of partner organizations. Partner organizations would need to be aware of protocols and guidelines during promotion.

- CIAPM should consider offering translated materials to be more accessible, starting with the Precision Medicine Primer.
- Consider the conclusions from the recent National Academies (NASEM) report on establishing a governance framework for science and technology innovations in health and medicine, while focusing on centering elements of equity and social justice throughout the innovation pathway.
 - As part of NASEM's research for this report, dozens of recent publications on technology development were studied to pin-point where, and whether, elements of equity were considered. Most frequently, the answer was "nowhere" and "never". The realization that social justice and community wellness had failed to be considered and implemented came only when something had gone wrong, after the technology had been approved by the government and released into the public.
 - Therefore, inviting community involvement in decision making is critical for equitable outcomes, for example, about how technologies would be developed, how they would be pursued, what the end product would look like, what the predicted reception may be. We know that the embarrassing truth is that such considerations are rarely made.
 - Therefore, a role that CIAPM can play to promote these practices is to make statements to communities and other funding agencies on how our RFPs are developed, and how we have conversations to ask about community concerns and opinions rather than waiting for issues to arise from neglect.
 - We recognize that it is a challenge to involve the community in in these considerations, not because it isn't important to do so or because they lack expertise that is perceived as important, but because it is important to approach these conversations with effort and care.
 - In conclusion, it is community involvement in addition to communication that CIAPM has been focusing on and should be highlighting as an example for other funding agencies that are involved in healthcare areas like technology development.

Public Comment

Dr. Ben Rubin: Regarding critical emerging topics, how might CIAPM contribute to state policy making and federal advocacy issues as they relate to AI and precision medicine?