



California Initiative to Advance
Precision Medicine

California Precision Medicine Advisory Council

Draft Meeting Summary, February 2022

Introduction of new council member

Dr. Devika Bhushan is an equity-focused pediatrician and public health practitioner who serves as California's Acting Surgeon General, focusing on three key cross-sector priorities: Adverse Childhood Experiences (ACEs) and toxic stress, early childhood development, and health equity. Previously, Dr. Bhushan served as the inaugural Chief Health Officer of the Office of the California Surgeon General.

Update from the Newsom Administration

Richard Figueroa, Deputy Cabinet Secretary

- California has a significant budget surplus, like last year.
- The depression budget item fits in well with the Newsom Administration's focus on behavioral health, particularly among younger individuals. This funding would allow us to apply more scientific rigor to the work that can then be amplified and leveraged by Medicaid and other systems.
- There is significant turnover in the legislature so the legislative outreach that CIAPM staff have done about precision medicine in general is vital to the legislature understanding the current CIAPM budget asks. It's important that they understand the context and how the research translates into other programs and policies.
- The Administration has released a framework for how to live with COVID, including PPI needs, vaccination needs, etc.
- May Revise will probably not make changes CIAPM's proposed budget items. We're hopeful that we'll be able to explain successfully why CIAPM's budget items are important investments in CA in general.

Sam Assefa, Director of Governor's Office of Planning and Research

CIAPM has two budget asks that were included in Governor Newsom's California blueprint: the depression research item, and the Underrepresented Minorities in Research item.

These budget asks are making their way through the legislative process. Last week, Julianne and Sam testified during the Senate's subcommittee hearing. The comments from the Senators were generally supportive, but they had questions as to:

- why the Initiative is based in OPR
- why the work couldn't be done by industry sponsors
- specifics about how the money would be spent
- the nexus between depression and precision medicine
- and metrics used to evaluate the program

Julianne provided strong, yet brief comments addressing the questions, and Shannon and Julianne followed up with detailed responses to the Senators in writing.

Accepted November 2021 meeting summary

- Discussed the state appropriations limit that may trigger with a budget surplus.
- Amended the guidelines regarding elections for the chair and vice chair
- Planned to hold the winter CPMAC meeting in Santa Clara in January in conjunction with the Precision Medicine World Conference.
- Presentation about the revamped Asset Inventory
- Reports back from working groups

Working Group report-back: Data Integration

EXPERT INTERVIEWS & MEETINGS

- CA Institute for Regenerative Medicine
CEO Dr. Maria Milan
VP Scient. Prog. Rosa Canet-Aviles
- CA Health and Human Services Agency
Undersecretary Marko Mijic
Chief Data Officer John Ohanian
Center for Data Insights & Innovation Dept. Director of the Elaine Scordakis
- CA Advancing & Innovating Medi-Cal (CalAIM)
CA Dept. Of Health Care Services
Chief Medical Information Officer, Dr. Linette Scott
- California Cancer Registry

- Co-Founder Dr. Hoda Anton-Culver
- UCSF SPOKE Knowledge Network
Professor Dr. Sergio Baranzini
- California Precision Medicine Consortium
Co-PI Dr. Lucila Ohno-Machado
- Loma Linda University
Professor Ariane Marie-Mitchell
- CA Homeless Coordinating & Financing Council
Executive Officer Julie Lo
- CA Board of Behavioral Sciences
Executive Officer Steven Sondgren
- CA Institute for Regenerative Medicine
Sr. Science Officer of Scientific Programs
Dr. Uta Grieshammer
Sr. Officer of Therapeutics & Strategic Infrastructure Geoff Lomax
- CA Office of the Surgeon General
Chief of Staff Matt Schueller
Chief Health Officer Dr. Devika Bhushan
Senior Clinical and Scientific Advisor Dr. Rachel Gilgoff
- CA Dept. of Health Care Access & Information
Dept. Director of Info Services Michael Valle
- CA Homeless Coordinating & Financing Council
Director of Research Jill Leufgen
- Lawrence Berkeley National Lab
Strategic Engagement Manager Marisa Rudolph
- Human Impact Partners
Co-Director Dr. Solange Gould
- Health Begins
CEO Dr. Rishi Manchanda
- Insure the Uninsured Project
Executive Director Katie Heidorn
Director of Health Policy Research Dr. Melissa Kraynak
- Cedars-Sinai Hospital
Director of the Community Benefit Giving Office
Erin Jackson-Ward
- US Dept. of Energy
Technology Manager Dr. Elizabeth Burrows
- Ancora Bio
CEO Dr. Steve Kanes
- University of Arizona
Tribal Health Programs Associate Director Stephanie Russo Carroll

Option 1: Advise

CA Dept. Health Care Access & Information (HCAI) All-Payer Claims Database

- General purpose:
 1. Report on health system spending, utilization, and performance
 2. Enhance state policy and regulatory analysis
 3. Inform the public about health care prices and quality
 4. Enable value-based purchasing and health care improvement
 5. Support public health monitoring and improvement
 6. Provide reliable data for health care research and evaluation

Launches July 2023

Researchers are represented by Dr. Cheryl Damberg, RAND Health Economist

Option 2: Advise

CHHS Data Exchange Framework

- By June 2024, health care entities must make their EHR data available in a secure and confidential manner via a Data Exchange Framework:
 - a single data sharing agreement
 - common set of policies and procedures that will govern the exchange of health information among health care entities and government agencies

Option 3: Build

CIRM-CA Surgeon General-CIAPM Knowledge Network

In partnership with the Office of the CA Surgeon General (OSG), create a knowledge network for CIRM- and CIAPM-funded research data that can link with other networks/datasets, including state administrative data for Real-World Evidence studies

- Advance outcomes research relative to ACEs, SDOHs, and other conditions to serve as a knowledge base to inform clinical and social services decision-making
- Promote open-access science

Accelerate the discovery-to-clinic pipeline

CIRM-OSG-CIAPM Knowledge Network:

Establish needs and priorities

- The new CIRM Strategic Plan commits to *“promoting the success of funded research by building infrastructure that organizes and democratizes data through knowledge networks and fosters shared usage of technologies through competency hubs.”*
- CIRM is beginning to consider infrastructure needs for data sharing/analysis
 - Work would begin mid-2023*
- Central Nervous System Consortium Workshop, Feb 24-25
 - Collaborating in the Cloud: Data Biosphere Structure
 - Genome Analysis Visualization and Informatics Lab-space (NHGRI)
 - Data Use Oversight System

- Three CIAPM-funded PIs will participate as discussants

Option 4: Test

CHHS/Coleridge Administrative Data Research Facility CHHS is working on a research data hub prototype and coupling that with IRB processes

Cloud-based research sandbox - researchers can play with data, engage stakeholders & partner with public agencies to affect policy

Unique Identifier: Nearly a proof-of-concept Master Patient Index

Linkage keys across the 5 major state programs:

Medi-Cal

TANF

Partnership with [ADRF \(Coleridge\)](#)

CalFresh

Child Welfare

Women, Infants, and Children

- Options 1 and 2 were seen as probable side projects.
- Option 4 was eliminated.
- Option 3 is of greatest interest, at least to begin.

Guideline Amendments

The guidelines were amended to

- Include Deputy Secretaries as eligible *ex officio* members from the California Health and Human Services Agency:

ARTICLE 2. Membership of Council and Desired Qualifications

1. The Council should consist of the following eleven members:

- a) The Surgeon General of California, *ex officio*
- b) The Secretary, *or a Deputy Secretary*, or an Assistant Secretary, of the Health and Human Services Agency, *ex officio*
- c) Seven 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

- Specify that amendments to the council guidelines must pass with 2/3 majority vote, and that council members not in attendance can vote via email up to 48 hours after the meeting:

ARTICLE 3. Council Organization (continued)

3. Quorum is achieved with seven Council members.
4. Six affirmative votes are needed for procedural motions to pass.
5. Amendments to the guidelines require 2/3 majority vote.
- ~~5.~~ 6. *Ex officio* members may vote and are counted toward quorum.
- ~~6.~~ 7. All motions that do not receive at least six affirmative votes during a meeting part are held open for 48 hours after that meeting part adjourns.
- ~~7.~~ 8. Council members who were not present at the time a motion was made may submit their votes for open motions up to 48 hours after that meeting part adjourns.
- ~~8.~~ 9. Council members who voted for a motion during a meeting may not change their vote via email.

All council members present voted in the affirmative for both amendments.

CIAPM items in the 22-23 Budget Proposal

- \$10M a competitive grant program to support precision medicine-based approaches to preventing, diagnosing, and treating depression. Grant recipients will use the principles of precision medicine to harness the power of computational analytics, next-generation genetic sequencing, and data sharing and aggregation to provide interventions that are tailored to a specific patient.
 - 3-5 projects
 - Up to \$3M per project
 - Project period: 36 months
 - Council participation: craft major points, suggest out-of-state reviewers

At the May 2022 council meeting members will be consulted about the RFP's major components, and will be asked to help with dissemination of the RFP and identification of out-of-state reviews.

- \$9.25M to increase participation in biomedical research (via the federal All of Us program) to better reflect California's diversity. CIAPM will lead a 5-year interagency collaborative to form a network, study/develop best practices,

create materials, host events to raise awareness, and increase participation among underrepresented communities in research studies.

- Commitments already from public agencies:

1. Dept. of Public Health
2. Dept of Aging
3. Dept of Developmental Services
4. Dept. of Rehabilitation
5. Mental Health Commission
6. Office of the CA Surgeon General
7. CSU Office of the Chancellor
8. UC Office of the President
9. CA Institute for Regenerative Medicine

Travel Reimbursement

- Before any travel reimbursements can be processed council members must submit a form STD 204 (the state's version of a W9).
- Booking travel
 - If driving is the best option, council members must use the trip calculator comparison tool to determine if it is cheaper to drive their own car and be reimbursed for mileage rent a car.
- During the trip keep all receipts, note maximum reimbursement amount for meals.
- After trip fill out and submit a Travel Expense Claim (TEC) & supporting documentation
 - Complete the TEC and scan receipts and documents exactly as specified.
 - Incorrect versions of receipts, accidentally obscuring parts of receipt while scanning, and misplacing information on the TEC are the most common reasons a travel expense claim will be sent back for revision
 - Include required supporting materials:
 - Screenshot of trip calculator comparison to show that the chosen travel method is the most efficient (within reason)
 - For personal vehicles, a Google map displaying door-to-door mileage; State will reimburse for the shortest route

- CIAPM staff will
 - Maintain a shared travel reference library with plain-language instructions, source material, and up-to-date copies of official forms.
 - Serve as an intermediary between OPR's travel coordinator and Council members.
 - Troubleshoot issues.
- More detailed information will be provided to council members and executive assistants.

Working Group report-back: Equitable Consent

Website: Equitable Engagement and Consent in Clinical Research

- Provide resources and best practices for clinical research stakeholders to increase participation by underrepresented subpopulations. Stakeholder groups include:
 - Sponsors
 - Researchers
 - Research staff
 - Potential and current research participants
 - Health care providers/Clinics

New Outreach Meetings

- Jazmine Garcia Delgadillo, DrPH, Health and Equity Program Manager, SGC, OHE-AC member
- Stanford Cancer Disparities Community Advisory Board
- Sara Bernstein, Manager, Research Information, National MS Society
- Maya Sabatello, PhD, Center for Precision Medicine and Genomics; Division of Ethics, Columbia University

Phased Rollout of Website Content

PHASE 1- expected summer 2022

Introduction

Existing Laws and Policies

For existing and potential research participants, excluding stories

PHASE 2- expected fall 2022

For researchers, excluding population-specific guidance

For research staff

PHASE 3- expected winter 2022

History and case studies

Population-specific guidance

PHASE 4- expected spring 2023
For Sponsors
For Healthcare providers
Stories of participants

| TASK | STATUS (as of May 2022) |
|-----------------------------------------------|-------------------------|
| Continue 1:1 and organization meetings | Ongoing |
| Create a granular timeline of rollout | Done |
| Draft dissemination plan | Done |
| Move ahead with added consultant and staff | In progress |
| Continue content development and organization | Ongoing |

Impact Assessment

Need

Convey importance and impact of CIAPM

Purpose

Compile, visualize, and analyze outcomes of California's investments in CIAPM to

- Improve communications
 - Cater to a general audience
 - Describe impacts in digestible and compelling formats
 - Amplify visibility
 - Create more opportunities to inform stakeholders
- Compare our mission against demonstrated impacts
 - Illuminate disconnects, gaps, or shortcomings
 - Adjust reporting to better capture informative data
 - Update RFP criteria to align with current priorities

Product: A dynamic webpage with information linked across projects

Content

1. Number of Californians engaged, diagnosed, supported, and/or treated
2. Amount of matching funds or leveraged resources
3. Number of patents or patent extensions
4. New or improved data sharing and analytical platforms, tools, or software
5. New validated technologies and approaches

6. Novel curricula for training programs
7. New or improved toolkits for healthcare providers
8. Number of press coverage or activity focused on the project
9. Number of publications in peer-reviewed journals and books
10. Number of presentations about the project, both to expert and public audiences
11. Number of trainees engaged in the project (post-doctoral fellows, graduate students, community health workers, technicians, medical students, undergraduate students, interns, residents, fellows, physicians, educators, etc.)
12. Number, size, and sustainability of collaborative networks, such as between researchers, communities, industry, universities, and philanthropy

Tailored Reporting

Calculate and provide information about the impact for specific regions, sectors, health conditions, methods, and networks.

Amplifying Perspectives and Experiences

Include stories and narratives that capture:

- A patient's experience participating in a CIAPM study
- How a community organization detected a local challenge and partnered with researchers to address it together
- Why a researcher chose their line of work
- What's unique about a CIAPM-funded project
- Why a business chose to provide in-kind support to propel research
- How projects can sustain momentum following the conclusion of a CIAPM grant
- What steps are involved in creating a new cross-sector network
- Deliberate centering of health and social equity as the primary goal

Discussion about administrative burdens on research participants will be added to the agenda for the next Equitable Consent Working Group meeting.