California Precision Medicine Advisory Council Meeting Summary, July 12, 2023

> **Key Actions**
> - Congratulations to Dr. Clara Lajonchere and Dr. Keith Yamamoto on their re-election as Council Chair and Vice Chair, respectively
> - As per the majority vote, the Q3 2023 meeting will be held in person in Sacramento (09/25/23)

1) Staff transitions
- *Farewell:* Co-Director Dr. Shannon Muir, Policy Fellow Bridgette Smith, and Intern Megan Neel
- *Introduction of new CIAPM Staff:*
  - David Reiner, PhD: Science Officer
  - Elyse Pennington, PhD: Science & Technology Policy Fellow
  - Beck Tran: Undergraduate Summer Intern
- *Delayed onboarding:* Equity Officer & Science Communications Officer

2) Conclusion of Mary Anne Schultz's term on the Council
- Thank you and farewell to Dr. Mary Anne Schultz for her dedicated three years of service as a Council member
- Mary Anne's unique perspective has been a valuable asset to this Council, as a health care practitioner for 48 years, faculty member and former department chair at CSU San Bernardino Department of Nursing, fellow of the American Academy of Nursing, and an active member of her community in the Inland Empire.

3) Elections
- *Eligibility:* All Advisors present, including current chairs, can be nominated to serve as the new chair & vice chair.
- *Term length:* Terms will begin at the end of this meeting,and will last for one year (next election: Spring 2024).
- *Responsibilities:*
  1. Lead council meetings
  2. Work closely with CIAPM staff to develop agendas and other materials
  3. Make decisions on behalf of the council if a council meeting is not possible
  4. Serve as resource to staff and fellow Advisors
  5. Approx. 5 hours/month
  6. The Vice Chair will be responsible for fulfilling the Chair's responsibilities when the Chair is unavailable
- *Nominees:*
  - Chair: Dr. Clara Lajonchere
  - Vice Chair: Dr. Keith Yamamoto
- *Unanimously approved:*
  - Chair: Dr. Clara Lajonchere
  - Vice Chair: Dr. Keith Yamamoto

4) Q3 2023 Meeting
- *Poll:* Whether to hold our next meeting in-person in Sacramento or virtually
- *Results:* In-person in Sacramento

5) Major Program Updates
   1. Led the development of a semi-finalist ARPA-H nationwide consortium (CIAPM helped develop a nationwide consortium for the new federal ARPA-H agency)
   2. CIAPM was featured during a legislative hearing of the Assembly Select Committee on Biotechnology
   3. USC MPA Students' Capstone Presentations in late April
   4. Advisory Council Working Groups are on hiatus until late 2023/early 2024

6) Remarks by the Governor's Cabinet *(Deputy Cabinet Secretary Richard Figueroa)*
   - *Mental Health Services Act:* Consistent with CIAPM's work on depression, the governor has a strong interest in behavioral health; earlier this week, the governor's proposal to modernize the Mental Health Services Act was reviewed by the legislature. It's a two-part piece of legislation to strengthen the emphasis on:
      1. Housing solutions and help for those exhibiting acute behavioral health issues
      2. Bond to build 10,000 treatment beds or units in California for those that have behavioral health issues and need permanent supportive housing.
   - *Biomanufacturing:* Under the governor, our state is the first to invest in producing low-cost insulin, and we are focusing now on making public investments to similarly increase naloxone nasal spray accessibility. It's been great to see the extent to which OPR engaged GO-Biz, Labor Agency, CDPH, OSG, and MHSOAC in the ARPA-H effort. California has much to offer nationwide cross-sector biomedical research. The potential for OPR's participation in other larger collaboratives has expanded, such as for biomanufacturing.
   - *Science budget update:* The Governor's January Budget Proposal did not include service reductions. Some of the expansions that Governor Newsom had proposed in the previous year were dialed back. The budget is going to be much tighter the next couple of years.

PROJECT UPDATES

1) Depression RFP *(Presented by CIAPM Staff David Reiner and Elyse Pennington)*

Overview: Competitive grant program to support precision medicine-based approaches to preventing, diagnosing, and treating depression
   - $9 million for research demonstration grants
   - 3-5 projects, up to $3 million per project, 36-month project period

Workflow: Added a new pre-selection stage for the following activities:
   1. Gathering information on depression and communities' experiences
      a. Conduct a gap assessment of the issue
      b. Conduct a landscape analysis of current funding opportunities
      c. Host a series of listening sessions, in collaboration with the Mental Health Services Oversight and Accountability Commission and local organizations and county health departments
      d. Release a public Request for Information to inform the development of the RFP
   2. Request for Proposals
      a. Out-of-state Selection Committee
      b. Letter of intent
      c. Concept proposal
      d. Full proposal

Preliminary Timeline:
   7/1/23: Release Notice of Funding Intent
   7/17/23: Release Request For Information
   July-Aug. 2023: Host listening sessions
   8/18/23: Request For Information responses due
   Oct. 2023: Letters of Intent due

Nov. 2023: Concept proposals due
Dec. 2023: Announce finalists
Feb. 2024: Full proposals due
Mar. 2024: Announce awardees

Gap Assessment & Landscape Analysis
- Purpose: Understand previous and current funding opportunities provided on depression research (to avoid repeating research)
- Our gap assessment and landscape analysis demonstrated racial inequities in depression research funding
- Of active NIH, NSF, CDC, and SAMHSA grants related to depression:
    - Few study Native Americans, AAPI, or Latinx people
    - Few focus on specific age groups (e.g. youth, elderly)
- Racial/ethnic minority (particularly AAPI, Native American), socio-economically disadvantaged, and sexual minority youth are underrepresented in depression studies and clinical trials
- Multiracial ethnic groups have the highest incidence of depression
- Cultural stigma prevents people from seeking treatment, so treatment rates vary by race/ethnicity

Request for Information
- Aim: to understand community needs to better address disparities and gaps within research funding
- Sample questions (13 total):
    - Which community or communities within California have the greatest need for improved depression outcomes?
    - How are depression and mental health viewed in your community or your community of expertise?
    - How could research help develop the type of strategies to improve depression prevention, diagnosis, and treatment and mental health that you would like to see in your communities?

Interagency Collaboration
- Partnering with the Mental Health Services Oversight and Accountability Commission (MHSOAC)
- Working together to host listening sessions with MHSOAC's community partners
    - Humboldt – Native American
    - Fresno – youth
    - Riverside – diverse group
    - Orange County - AAPI

Discussion

→ Diana Ramos:
- *Helpful reference: listening sessions for the Children Youth Behavioral Health Initiative ($4.7B investment)*
- *Q: Is there a target age group? (The Children Youth Behavioral Health initiative is focusing on 0- 24 years old) A: None yet; we will include any focuses on demographics, age, racial, ethnic group, etc. based on information we gather from the listening sessions and the RFI*
- *One of my initiatives strives to improve maternal mortality and morbidity, especially the preventable and most common causes for maternal death postpartum (one year) are suicide, depression, substance abuse.*
- *There is a good study published in November about central valley farm workers of Hispanic origin*
- *Partnering with some of the bigger health systems (ex. Kaiser) and Medicaid populations could be a good starting point.*
- *One of the mental health initiatives is introducing 40,000 new community health workers.*

→ Oliver Keown: Scaling interventions
- *Interested in building funding opportunities around scaling interventions.*

- *For example, new research shows that the risk of depression doubles based on the sleeping patterns of a year prior. So, young Californians with wearable technology to measure our sleep health may be additional stakeholders in the technology sector.*

→ Keith Yamamoto: Electronic health records
- *UC Data Commons: Reduces doctor's notes through natural language processing to better structure it, which then makes it easier to pull out that information.*

→ Ysabel Duron: Farm worker organizations
- *If you are focusing on youth in the Central Valley or Fresno, it would be good to intersect with farm worker organizations to include the children of farm workers, since they have been affected by the trauma experienced by their parents (ex. Immigration status, low income, health issues from exposure to toxins in the fields).*

→ Ysabel Duron: Use of Latinx
- *Be aware that some communities, especially older generations, may feel that this term has been superimposed on them, the way terms like "Hispanic" and "Latino" previously have.*
- *Pew survey data shows that the majority of Latinos do not prefer the term "Latinx" (with the exception generally being younger people)*
- *Bottom line: Ask communities about the terminology they want to be represented by.*

→ Ysabel Duron: All of Us research project
- *Of the ~70,000 Latino participants in the All of Us research project, there are representatives of Latino enrollees from every state but Massachusetts. It may be interesting to take a closer look at that data to see what is happening in Massachusetts.*

Industry Partnerships
1) How should teams include industry partners?
   - Key team members?
   - Collaborators?
2) What constitutes industry partnership?
   - Involvement in experimental design?
   - Committed discounts on services/products?

→ Fatima Munoz: Preventing duplication of efforts
- *Communication with and between three main areas like community health centers, health services organizations, and community outreach programs is important especially because they may each be focused on different levels of prevention and intervention.*

→ Diana Ramos: Broaden definition of industry partners
- *Be open-minded about what constitutes an industry partner*
- *Ex. In the mental health space, I recently began working with those at the Calm application and I never would have thought to approach them. This partnership has the potential to open up new avenues of innovation and opportunities while we introduce them to our areas of focus.*

→ Keith Yamamoto: Industry vs. private sector
- *I agree that we should keep the industry definition broad*
- *One way to keep it broad is to rename "industry" partners to "private sector"*

→ Clara Lajonchere: Inclusion of healthcare providers
- *Q: In the parameters for submitting letters of intent, do we include healthcare providers or do we limit it to private companies?*
- *If we don't include healthcare provider organizations at some point they are going to be the ones providing some service or follow-ups to the participants and community, and then should be receiving resources and be part of the planning to bring perspective to the research project.*

→ Clara Lajonchere: For-profit partners
- *We specified that profit company partners would not be able to tap any of the money ($9M)*

- *Q: What constitutes an industry partnership? Is it involvement in experimental design, or committing to providing discounts on services and products? What will be the legal aspects of how the money can be spent?*
- *If there is someone on the vendor team that wants to contribute to experimental design, I think that's fine as long as they're not receiving a salary.*

→ **Julianne McCall: Industry partnerships**
- *Governor Newsom does not want to see right public funding shoring up what industry would have already paid.*
- *Q: What does partnership mean beyond serving as a vendor and providing a discount?*

→ **Oliver Keown: Industry partnerships**
- *We should be explicit that industry partnerships need to contribute beyond a vendor relationship, since these companies have a wealth of expertise and access.*
- *Since the innovation economy forces companies to be at the cutting edge, I think that private sector vendors will have critical scalability capabilities that will be important for the longevity and impact of our funded research projects.*
- *In an ideal world, the RFP would require a buy-in on the outcome or insights so that industry partners contribute to scalable private sector innovation, so that the outputs of this research can be brought to broader populations.*

Depression RFP: Key Discussion Points
- D. Ramos suggests including the postpartum pregnant community (and other adults) to increase diversity in age of participants
- D. Ramos suggests looking up the listening sessions at the Children Youth Behavioral Health Initiative ($4.7B investment); shared publicly on their website
- D. Ramos has offered connect CIAPM to the farmworkers in Fresno
- D. Ramos has offered to attend/serve as a resource for the listening sessions
- Y. Duron suggests looking into including farm worker organizations in the central valley to reach out to/include their children in the study
- Y. Duron suggests deferring to participant communities to choose representative terminology (ex. Latino vs. Latinx)
- Overall consensus to keep the definition of industry partners broad (ex. Grouping the partnerships under "private sector")
- Overall consensus that industry partnerships should require engagement beyond a vendor relationship

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2) ARPA-H Nationwide Health Innovation Network *(Julianne)*
Advanced Research Projects Agency for Health

Overview
- **Mission:** Accelerate better health outcomes for everyone.
- **Challenges:**
    1. Many Americans live too far from healthcare centers.
    2. Biotech centers aren't co-located with customers that need treatment the most.
    3. Numerous diseases disproportionately impact vulnerable populations.

Initial Mission Focus Areas
1) **Health Science Futures** *(Expanding what's technically possible)*
    ○ Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.
2) **Scalable Solutions** *(Reaching everyone quickly)*
    ○ Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.

3) **Proactive Health** *(Keeping people from being patients)*
   - Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.
4) **Resilient Systems** *(Building integrated healthcare systems)*
   - Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.

Hub and Spoke Model
- **The 2023 Consolidated Appropriations Act** directs the agency to est. sites in at least three geographic areas.
- The hub and spoke model will form a network of people, institutions, and capabilities across the country.
  - **Hub:** To ensure the active transition of health innovation in an expedient, cost-effective, accessible and sustainable manner that reaches all Americans.
  - **Spoke:** To ensure that Americans in every community benefit from ARPA-H solutions. Spokes are connected to appropriate hubs on an ongoing basis.

Request for Consortium Agreement: A call to identify ARPA-H sites
1) **Stakeholder and Operations Hub:** To engage key federal stakeholders to ensure success of program offerings from their inception. These partners contribute regulatory, legislative, and executive expertise to ARPA-H's efforts.
2) **Customer Experience Hub:** To focus on customer experience and drive user testing, adoption, and access to ARPA-H projects. The consortium will take a human-centered approach to design products and services that people need and want to use.
3) **Investor Catalyst Hub:** To help ARPA-H programs navigate the complexities of the business, transition, and regulatory landscape and provide resources to help performers bring their ideas to market.
   - The goal for this hub is to ensure performers overcome business challenges, grow their operations through follow-on funding, and bring their products to market.
   - Some examples of activities might include:
     - Office and lab space
     - Mentorship and support
     - Business development and networking
     - Education and training
     - Regulatory and legal support
     - Intellectual property protection

Discussion (Closed Session)

Public Comment: none