

# Real Life™

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Vice President, Medical Affairs and Policy

Update on CCCE and Roadmap on Access and Affordability

March 28, 2023

**CIRM**  
CALIFORNIA'S STEM CELL AGENCY

- Community Care Centers of Excellence
- Roadmap on Access and Affordability
- Patient Support Program

- Small group discussions intended to inform the development of CCCE Concept Plan.
- Three sessions: San Joaquin Valley (Clovis/Fresno), Inland Empire (Riverside), Coachella Valley (Palm Desert).
- Discussion themes include (1) capacities to support clinical research, (2) workforce education and training needs, and (3) resources to support patient/community outreach, education and engagement.
- 53 participants including: health care providers, elected officials, community-based organizations and patient advocates.


- Clinical sites have partnerships with CIRM-funded academic centers and research experience.
- Providers and patient advocates want to be part of the “CIRM experience.”
- CBOs and elected officials emphasize the need to build relationships and trust (relational engagement not transactional or paternalistic).
- Create opportunities for innovative communications using non-traditional messengers (e.g., draw on younger generations in CIRM training programs).

Why are we doing this?

Proposition 14 charges the ICOC, based on recommendations from the AAWG, with developing policies and programs to make treatments and cures arising from CIRM research available and affordable.

The roadmap will include a strategy for gathering data and information to support reimbursement, a plan to engage policymakers and regulators and the development of novel healthcare delivery models through the Alpha Clinics and Community Care Centers of Excellence.

 **DELIVER A ROADMAP FOR ACCESS AND AFFORDABILITY OF REGENERATIVE MEDICINE FOR ALL CALIFORNIA PATIENTS**

  
**Facilitate Reimbursement and Limit Patient Expenses**

  
**Support New Payer Models**

  
**Address State Policy Issues**

  
**Build Clinical Resources**

**Patient Support Services**

**Alpha Site Coordination and Alignment**

**Patient Navigator at CCCEs**

**Coverage Analysis, Insurance Support, Co-Pay Assistance, Access and Appeals**

**Engagement with Payers**

**Performance-Based Models**

**Introduce New Payer Mechanisms for Orphan Products**

**Risk Pools/Coalition Partners**

**Creation and/or endorsement of new State policy for C&GT**

**Treatment across state lines**

**Inpatient vs. Outpatient reimbursement**

**Align to Gov Plan on Office of Health and Affordability**

**Alpha Clinics and CCCE**

**Patient and post-marketing Registries and Data (RWE, HEOR)**

**Accelerate Advocacy at community level; Medical Education**

**State and Federal authorized treatment centers**

# How are we approaching the Roadmap to Access and Affordability?

We are approaching the roadmap as a 5-year plan.

We will have specific concept plans for the next 5 years to ensure these roadmap concepts are completed.

During this 5-year plan, we are also going to acquire additional information to create a more robust program.

# Examples of activities we need to enable access and affordability

These are the activities we are going to undertake:

- Engage With Payers and other Key Stakeholders
- Conduct Landscape Research on CGT-related Policy Issues
- Aggregate and Analyze Available Real-world Data
- Set Goals for Each Roadmap Activity
- Develop Metrics to Assess the Progress of Programs



**Thank you and Discussion**

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## Rationale:

- Feasibility and flexibility in awarding and financing Provider Agreements.
- Establish and utilize a review process for AAWG-recommended programs based on existing Grants Working Group model.
- AAWG Review Process in Alignment with Grants Working Group.

## Minor revisions:

A few additional edits have been included in the concept document that represent the change from RFP to RFA.

- Minor edits to definitional terms.
- Clarity on award amount and duration of funding through the program.
- California operating license, operating location and demonstration of solvency.
- Removal of unnecessary operational information intended for RFA.

CIRM requests approval of the proposed revisions to the Patient Support Concept Plan from RFP to an RFA.