

Real Life™

Geoffrey Lomax DrPH

Associate Director, Medical Affairs & Policy

CIRM Scientific and Medical Accountability
Standards Working Group

January 16, 2024 South San Francisco

CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

Accelerating world class science
to deliver transformative
regenerative medicine treatments
in an equitable manner to a
diverse California and world



- Provide an overview of CIRM's Proposed Community Care Centers of Excellence (CCCE) Program
- Describe the program's outreach and engagement activities
- Highlight questions for program implementation

Community Care Centers of Excellence are infrastructure described in Proposition 14.



INFRASTRUCTURE

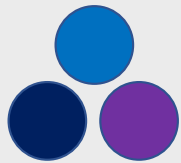
Establish the Community Care Centers of Excellence Program to expand the capacity of the Alpha Stem Cell Clinic Program to promote access to human clinical trials and the accessibility of treatments and cures arising from institute-funded research for patients in California by establishing geographically diverse centers of excellence to conduct clinical trials and to seek to make the resulting treatments and cures broadly available to California patients.

Needs Assessment Phase

Board Review

Application Phase

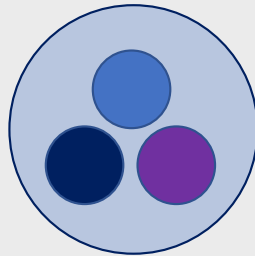
Listening Sessions
and Interviews



- Central Valley
- Inland Empire
- Coachella Valley



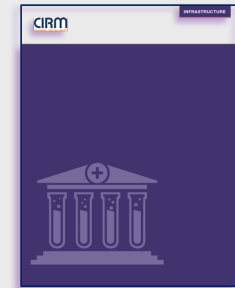
Statewide
Public Workshop



- In-Person and Virtual



- Draft Concept
- Consult Science Subcommittee
- AAWG and ICOC



- Posting
- Webinar
- Engage Applicants

Oct 22 – Mar 23

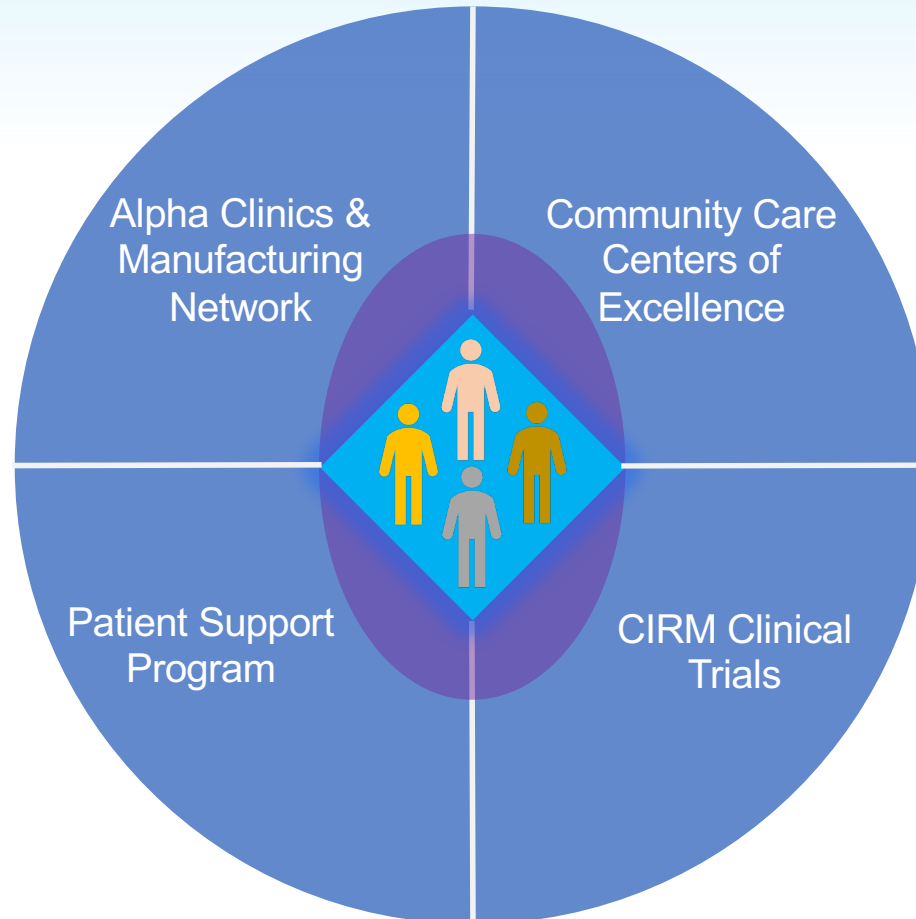
June 2023

Q3-Q4 2023

Early 2024

CCCEs will Coordinate with CIRM's Clinical Programs and Infrastructure

- Nine Awards, 10 Medical Centers
- Supporting CIRM-Funded Clinical Trials
- Includes Manufacturing Capacities
- Status: Active



- Bring CGT Clinical Capacity to Communities
- Address Social Determinants Impacting Participation
- Status: Draft Concept Plan

- Address Financial and Logistical Barriers
- Improve Patient and Research Outcomes
- Status: Application open

- 96 CIRM-Funded Clinical Trials
- Optimal Care for Unmet Medical Needs
- Status: Active and ongoing

CLINICAL

- Support and/or conduct clinical trials
- Deliver approved regenerative medicine products
- Referral hub for Alpha Clinics and Patient Support Program

CAREER DEVELOPMENT

- Adapt and deploy training curricula
- Serve as a placement site for CIRM trainees
- Support CHW and Patient Navigator programs

COMMUNITY ENGAGEMENT

- Engage patients and communities
- Partner with community-based organizations
- Focused efforts to engage under-represented populations

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-
- What ethical principles or practice guidelines should inform engagement programs?
 - Are there specific considerations for engaging historically under-represented populations?
 - What types of training are recommended?
 - What role should CIRM play in overseeing and/or evaluating engagement programs?

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- Provide an Overview of CIRM's Patient Support Program (PSP)
- Describe the program's operational requirements
- Highlight questions for program implementation

Cell and gene therapy trials are becoming more demanding on patients and require additional support beyond routine costs for patients and their families.

New Patient Assistance Programs have emerged to address bottlenecks associated with gene therapy/gene-edited trials.

The objective is to launch a Patient Support Program (PSP) to provide logistical and financial support to patients seeking to enroll in clinical trials. The overall aim is to improve access and retention in clinical trials with an emphasis on financially-eligible underserved populations.

- 1. Patient Intake and Navigation:** Call center capable of addressing inquiries and referring patients to CIRM-funded programs and clinical sites.
- 2. Assessing Patient/Family Financial Eligibility:** Work with CIRM, sponsors, and clinical trial sites to determine eligibility.
- 3. Facilitate Support Services:** Support patient access to travel, childcare, meals, or other trial-associated expenses. Optimally, without the patient incurring out-of-pocket costs.
- 4. Maintain Accounting Systems:** Maintain systems sufficient to document costs and ensure appropriate use of CIRM funds.

FINANCIAL SUPPORT

- Cover out-of-pocket costs
 - Provide logistical support
 - Expand services based on program evaluation
-
- How does the CIRM PSP align with norms for patient support and reimbursement?
 - Are there guidelines for the timing of disclosure of patient support programs (e.g. during consent, after enrollment)?
 - Should the level of services available through a PSP be available to all patients in the clinical trial?
 - How important are patient support services for ensuring equity and inclusion in clinical research?
 - Are there critical needs in CGT trials that are not addressed under the current framework?

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