



California Institute for Regenerative Medicine

Community Care Centers of Excellence Concept Plan

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OUR MISSION

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





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



INFRASTRUCTURE

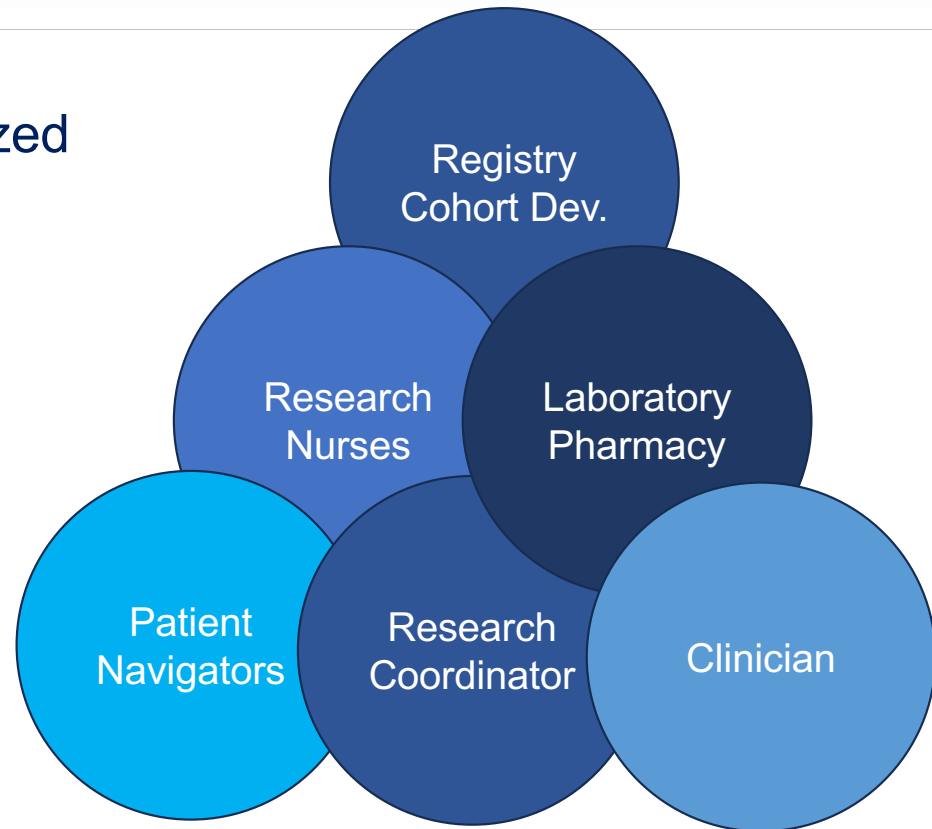
Establish the Community Care Centers of Excellence Program to expand the capacity of the Alpha Stem Cell Clinic Program to promote access to human clinical trials and the accessibility of treatments and cures arising from institute-funded research for patients in California by establishing geographically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



Infrastructure: The resources (such as personnel or equipment) required for an activity.

CGT and Clinical Research Specialized Needs (disease agnostic):

- Sponsor engagement
- Patient education
- Regulatory & coverage analysis
- Product management
- Data management



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

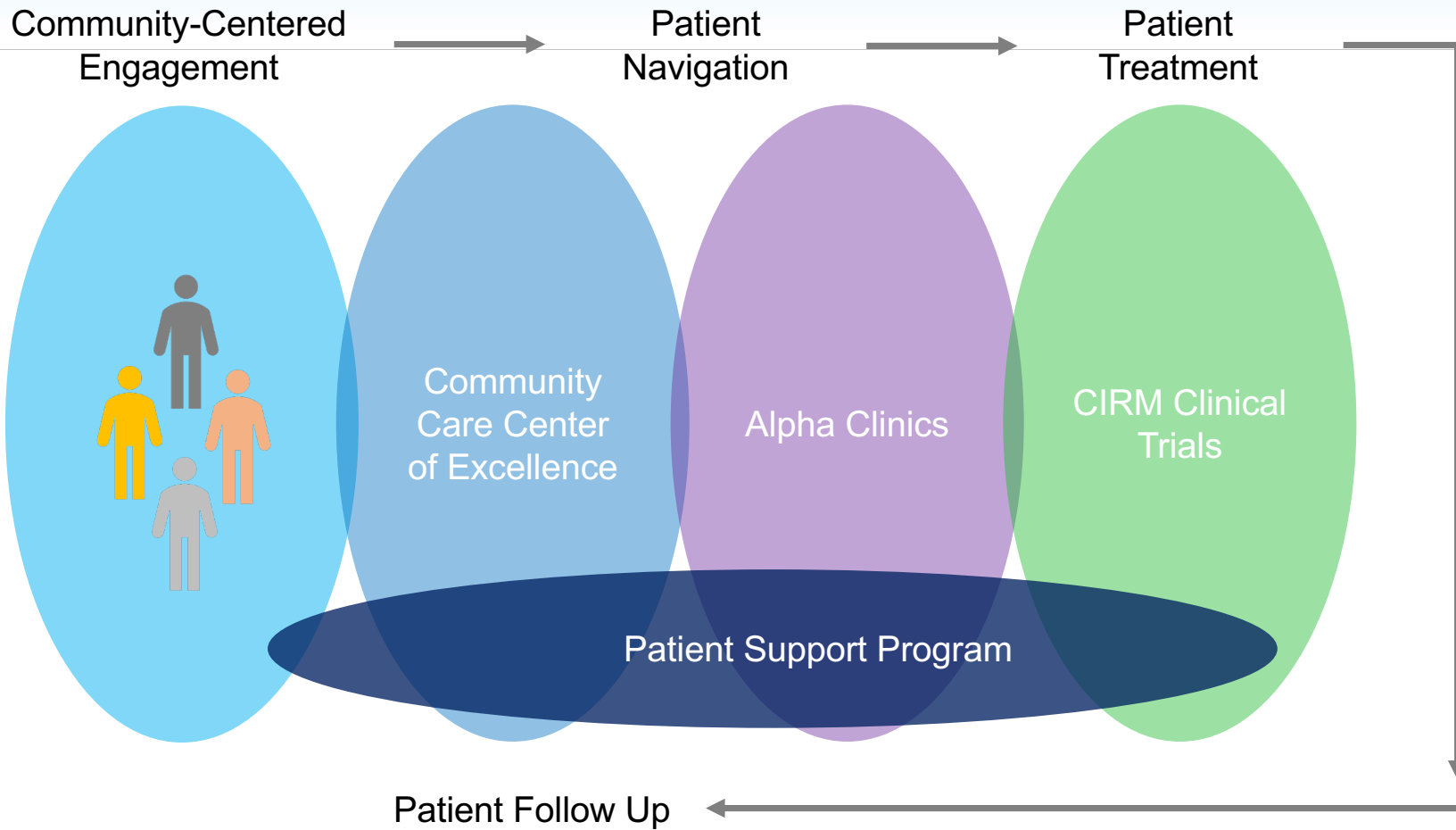
- Address Financial and Logistical Barriers
- Improve Patient and Research Outcomes
- Status: Application open



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

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

Example: CCCE as an Access Facilitator



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

CIRM has performed a state-wide needs assessment and recognizes that making treatments widely available to California patients will require approaches attuned to social determinants that vary both geographically and within defined sub-populations.

Provide career development opportunities for . . . community health workers, patient navigators, or other medical professionals that are integral to making regenerative medicine clinical trials or treatments accessible.

Propose targeted interventions aimed at reducing disparities in referrals to clinical trials with the overall aim of increasing the participation rates of medically underserved patients.

- Clinical Operations: Have a licensed and certified healthcare facility with a demonstrated capacity to support **human subjects protocols** in a health research context. Have current capacity or be in the process of developing capacity to **support clinical research** protocols involving cell, gene, or regenerative medicine treatments. Do not administer unauthorized stem cell treatments.
- Career Development: Have a demonstrated capacity to support the education, training, and career development of physicians, nurses, research coordinators, community health workers, or other health/medical professionals.
- Outreach and Engagement: Have a demonstrated track record of conducting or coordinating health education, research, and engagement activities. Create partnerships with Community-Based Organizations (CBOs) to support program objectives.

- Clinical Operations:
 1. **Support Site**: Supporting access to regenerative medicine clinical trials or approved products.
 2. **Support and Delivery Site**: Develop the capacity to deliver investigational or regenerative medicine products during the award period, and do not administer unauthorized stem cell treatments.
- Career Development: Adapt, apply, or otherwise utilize EDUC and other CIRM training resources. Serve as a placement site for CIRM scholars and trainees. Integrate regenerative medicine into navigator and community health worker certification programs. CME programs for primary care physicians and providers.
- Outreach and Engagement: Extend, develop programs, and create partnerships with Community-Based Organizations (CBOs) to support clinical research or care, career development, and community engagement.

| | Alpha Clinic | CCCE |
|---------------------------|---|---|
| <u>Clinical:</u> | <ul style="list-style-type: none"> • Conducting CLIN2-eligible trial | <ul style="list-style-type: none"> • Supporting CLIN2-eligible trial • Developing capacity to conduct CLIN2-eligible trial |
| <u>Training:</u> | <ul style="list-style-type: none"> • Creating and delivering training program(s) | <ul style="list-style-type: none"> • Applying programs for career development • Serving as a placement site for CIRM trainees |
| <u>Engagement:</u> | <ul style="list-style-type: none"> • Focus on clinical trial engagement and navigation | <ul style="list-style-type: none"> • Clinical trial engagement and navigation • Includes community engagement for CIRM programs (CLIN and others) • Includes Community-Based Organizations (CBOs) partnerships |

- Human Subjects Protocols: Research (clinical or otherwise) involving human participation requiring review and ongoing oversight by an institutional review board (IRB) and other oversight bodies may be required.
- Unauthorized “Stem Cell” Treatments: The applicant organization must not provide direct-to-consumer fees for service interventions involving “stem cell therapies” subject to the notice requirements of CA Bus & Prof Code § 684 (2018).
- Research Ethics Training: Include research ethics training for partners consistent with requirements for clinical and social science research.
- Standards Working Group Review: CIRM SWG to review the concept plan.

- **Engagement and Navigation for Underrepresented Populations**
 - Expanded Reach: Dedicated budget resources for community-based organizations.
 - Sustainability: Develop education and navigation programs around reimbursable activities. Specific leverage opportunities include patient navigator and Community Health Worker (CHW) certification programs.
 - Focus: Propose targeted interventions aimed at reducing disparities in referrals to clinical trials with the overall aim of increasing the participation rates of medically underserved patients.
 - Build Competency: CIRM-mediated engagement network to identify training requirements and practice-based solutions. Integrate lessons learned across Infrastructure Programs.
 - Internal Resources: Medical Affairs proposes program planning and evaluation expertise.

- **Building Partnerships with Alpha Clinics:** Relationships have emerged from the needs assessment process.
- **Manufacturing Network Partnerships:** Connecting potential applicants to CIRM's Manufacturing Network and Alpha Clinics.
- **Coordination with CIRM Education Programs:** Utilize Educational Portal to support training and career development. Career development opportunities will be publicized through the portal.
- **Engaging Patients with Rare Diseases:** Utilize Alpha Clinics cohort development tools and conduct pre-application webinars to connect applicants to disease advocacy organizations.

- A budget allocation of \$60.2 million is proposed (P-14 Authorizes up to \$78M)
- The budget is designed to support program (1) core operations, (2) community partnerships, (3) building renovation, and equipping facilities over a five-year duration
- The total five-year budget proposal is an estimate assuming the following distribution of awards:
 - Three “Support and Delivery” awards at \$10.054 million per award
 - Four “Support” awards at \$7.5 million per award

CIRM requests approval of the Community Care Centers of Excellence Concept Plan with a budget allocation of \$60.2 million.

| Cost Category | Maximum Annual Per Award | Maximum Funding Request Per Award (All Years) |
|------------------------------|--------------------------|---|
| Core Operations | \$1.08M | \$ 5.4M |
| Community-based Partnerships | \$0.25M | \$ 1.0M |
| Facilities Funds | | \$ 2.5M |
| Indirect Costs | \$0.22M | \$ 1.12M |
| Total | | \$ 10.2M |