



California Institute for Regenerative Medicine

Community Care Centers of Excellence Concept Plan

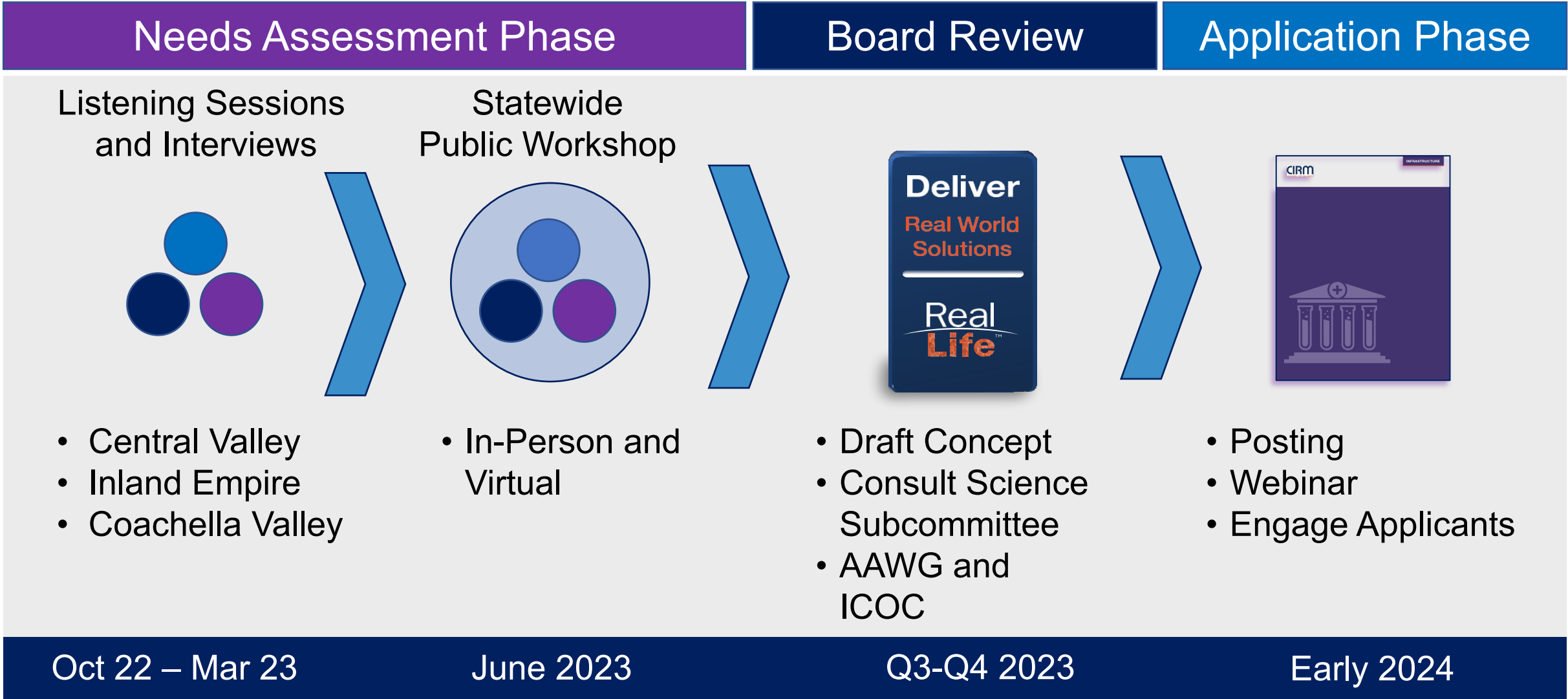
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Science Subcommittee - November 30, 2023



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.



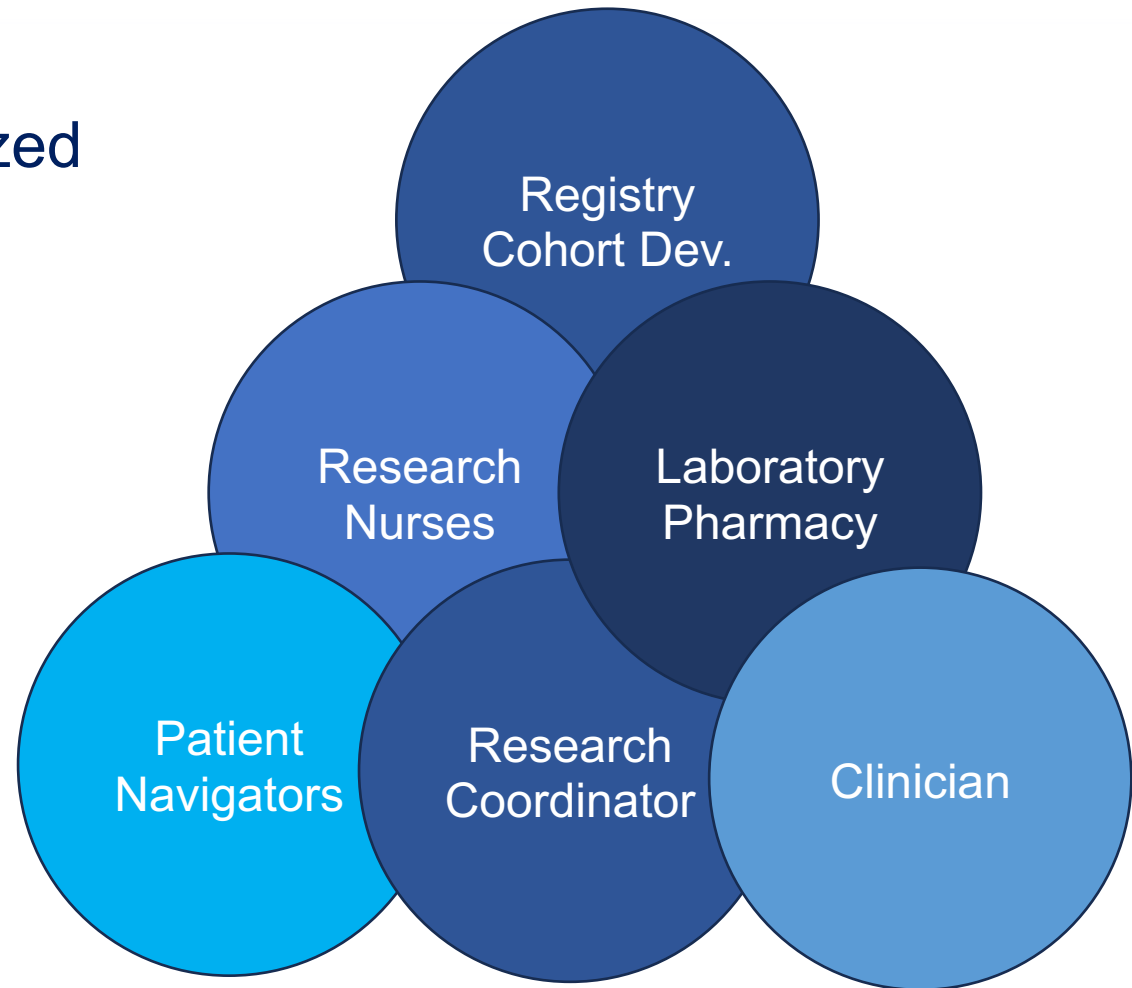
The CCCEs are designed to serve as a hub for expanding access to clinical trials, regenerative medicine treatments and CIRM education and training programs. A strategic aim is to provide equitable access to communities and populations that would otherwise have more limited opportunities in the absence of these centers.



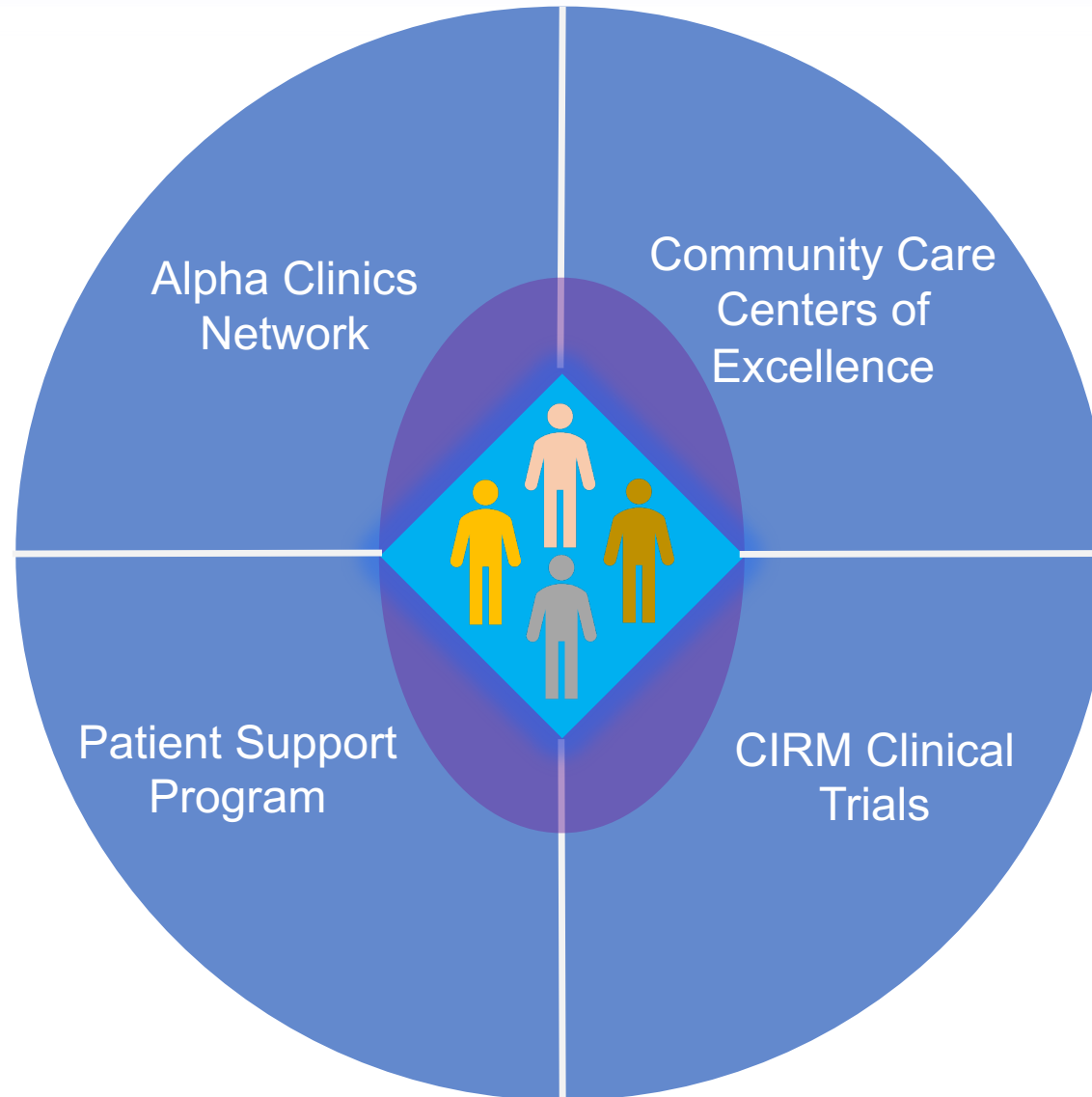
Infrastructure: The resources (such as personnel or equipment) required for an activity.

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
- Status: Active

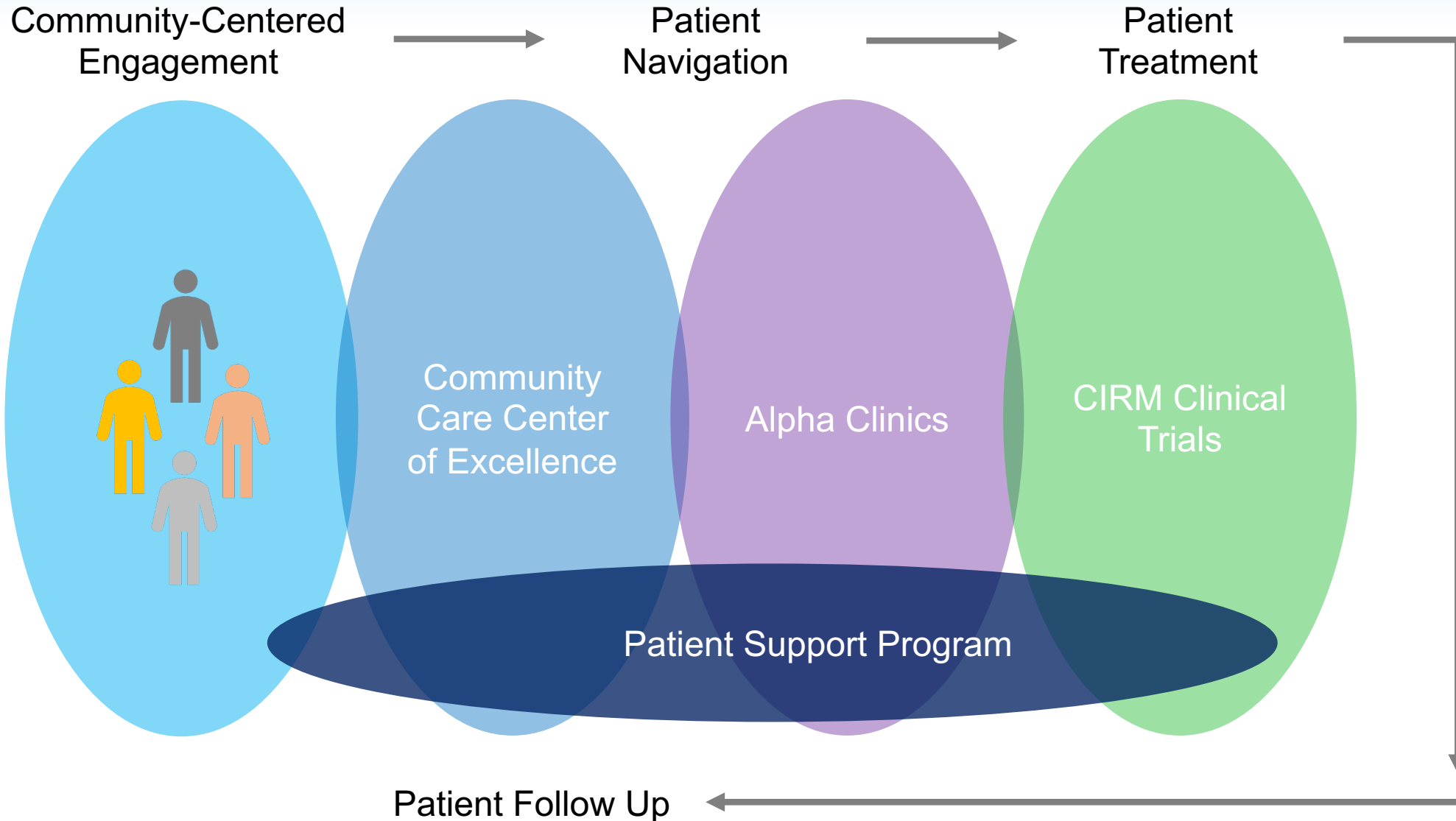


- Bring CGT Clinical Capacity to Communities
- Address Social Determinants Impacting Participation
- Status: Draft Concept Plan

- 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

Example: CCCE as an Access Facilitator



- 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 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.
- 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 fee 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.

- Sustainable Education and Navigation: Develop education and navigation programs around reimbursable activities. Specific opportunities include patient navigator and community health worker certification programs.
- Coordination with CIRM Education Programs: CIRM is developing an 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
- The budget is designed to support program (1) core operations, (2) community partnerships, (3) building renovation, and equipping facilities for 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