



California Institute for Regenerative Medicine

Community Care Centers of Excellence Informational Webinar

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Submitting Questions

- How to Submit:
 - Use the Q&A feature in the webinar platform to submit your questions.

During the Webinar

- Categorization:
 - Questions will be categorized by topic to ensure a streamlined discussion.
- Prioritization:
 - We will prioritize the most relevant and frequently asked questions.

Please send unanswered to ccce@cirm.ca.gov

- Slides and FAQ will be available on our website <https://www.cirm.ca.gov/researchers/funding-opportunities/infrastructure/>
- A recording of the webinar will be available on our CIRM TV YouTube channel <https://www.youtube.com/user/CIRMTV>

OUR MISSION

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



INFR8: CIRM Community Care Centers of Excellence



04.03.24

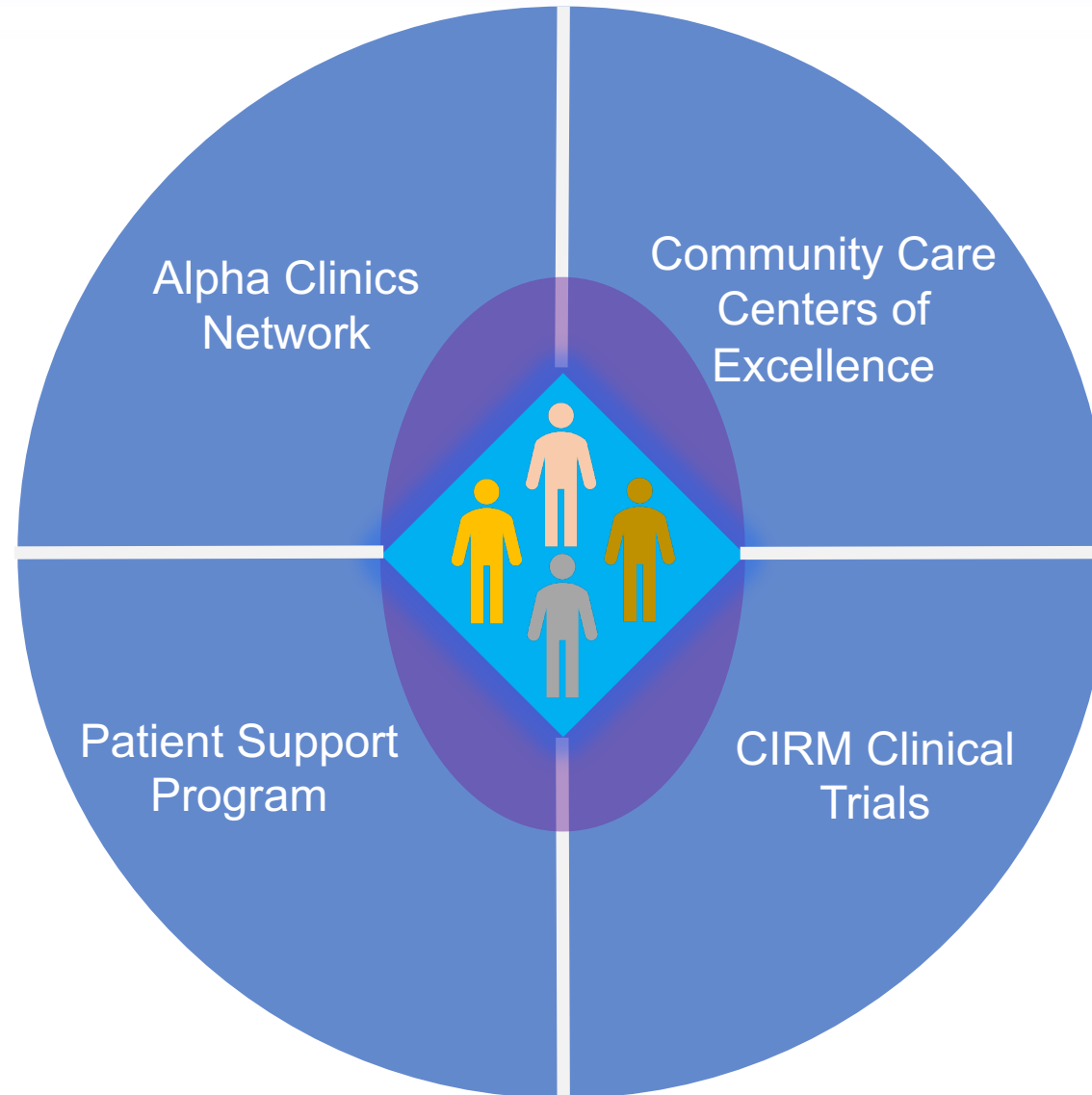
- Application available in the grants management portal no later than May 31 2024.
- Applications are due by 2 PM on August 15, 2024.
- Background Materials
 - June 22, 2023 Public Workshop
 - January 25, 2024 ICOC

<https://www.cirm.ca.gov/board-and-meetings/public-meetings/>
- Send email correspondence to: ccce@cirm.ca.gov

The objective of CCCE program is to establish geographically diverse and culturally responsive centers of excellence to:

1. Support access to FDA-authorized clinical trials involving cell, gene and/or approved regenerative medicine treatments,
2. Make these treatments broadly available to California patients, and
3. Provide workforce career development opportunities.

- Nine Awards
- Supporting CIRM-Funded Clinical Trails
- Status: Active



Alpha Clinics Network

Community Care Centers of Excellence

Patient Support Program

CIRM Clinical Trials

- Bring CGT Clinical Capacity to Communities
- Address Social Determinants Impacting Participation
- Status: RFA open

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

- CIRM-Funded Clinical Trials (100+ funded to date)
- Optimal Care for Unmet Medical Needs
- Status: Active and ongoing

106 CIRM-FUNDED CLINICAL TRIALS

- All
- Blood
- Blood Cancers
- Bone
- COVID-19
- Diabetes
- Eye
- Heart
- HIV/AIDS
- Kidney
- Neuro
- Solid Cancers
- Other

Disease Areas	Investigator	Organization	Phase	Trial Status	Target Enrollment	Detail
Severe Combined Immunodeficiency, Artemis deficient (ART-SCID)	Mort Cowan	University of California, San Francisco	Phase 1	Recruiting	25	→
Lung Cancer	Steven M. Dubinett	University of California, Los Angeles	Phase 1	Recruiting	24	→
Kidney Failure	Dr. Everett H. Meyer	Stanford University	Phase 1	Recruiting	22	→
Type 1 diabetes	Peter Stock	University of California, San Francisco	Phase 1/2	Recruiting	8	→
Brain Cancer Breast Cancer	Dr Saul J Priceman	City of Hope, Beckman Research Institute	Phase 1	Recruiting	39	→
Corneal Damage	Dr. Sophie X Deng	University of California, Los Angeles	Phase 1	Recruiting	20	→



200+ CLINICAL TRIALS

1000+ PARTICIPANTS

40+ DISEASE AREAS



Alpha Clinic



UC San Diego
SANFORD STEM CELL INSTITUTE
Sanford Stem Cell Clinical Center



USC+CHLA
Alpha Clinic

- 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 and develop programs and create partnerships with CBOs to support clinical research or care, career development and community engagement.
- Community-Based Partnerships: Applicants must allocate a minimum of \$625,000 in the award budget for community-based partnerships. **Applicants should propose at least one partnership with a community-based organization(s) to support clinical research, career development and/or outreach and engagement.** Emphasis should be placed on supporting activities that reduce disparities and support broad representation in clinical research such as increasing referral rates for underrepresented populations or groups with unique needs such as native Americans and veterans.

- Five-year funding
- A Clinical Trial Support Site may request a total award amount of up to \$7.5 million per award.
- A Clinical Trial Support and Delivery Site may request a total award amount of up to \$10.054 million per award.

Applicants may allocate funds from the total award amount to support facilities renovation and/or equipment. Funds may be utilized for renovating existing facilities or acquiring equipment integral to the operation of a Community Care Center of Excellence.

- Renovation of facilities necessary for the delivery of investigational or approved products to patients.
- Purchasing or leasing equipment for the manufacturing or processing of products, including but not limited to mobile manufacturing facilities.
- Renovation of facilities necessary to navigate, screen or follow up with patients who are participating in clinical trials or receiving approved treatments.

- Trust: Trust and trustworthiness of the profession (professionals, researchers, healthcare systems) by the individual and the community are important considerations during communications and collaborations between researchers and participants/community groups.
- Respect: Patients, participants, and communities should be seen and treated as important partners in research and should know what they deserve and should expect from the partnership and research. Each other's expertise is recognized in a bidirectional co-learning process.
- Capacity-building (benefit): Partnerships should serve to build the capacities or field strength of all partners. In the context of this program, one important outcome is developing sustainable capacity to address barriers or conditions that contribute to disparate access to treatments.

- How will your site will coordinate with network partners? (Alpha Clinics and Patient Support Program) to expand enrollment in clinical trials?
- How will your site propose collaborations with Alpha Clinic sites or other CCCE applicant?
- How will your site add and/or expand value to CIRM's existing infrastructure network?

Applicants are encouraged to propose holistic and integrated approaches for satisfying the objective of this program. Specifically, consider how your clinical, career development, community-based partnership and network development initiatives can work in tandem or synergistically to enhance the capacity of CIRM's Clinical Infrastructure Network to treat patients and address barriers or conditions that contribute to disparate access.

Applicants must provide a statement outlining how their Community Care Center of Excellence will:

- Support underserved populations in clinical trials
- Incorporate diverse perspectives in implementation
- Promote diversity, equity, and inclusion in research efforts

Sharing knowledge is crucial for the success of CIRM Infrastructure Programs in advancing regenerative medicine.

All CIRM awards require data or knowledge sharing plans, including collection, curation, and preservation of data.

Applicants must outline plans for capturing operational information related to core competencies, training programs, and outreach efforts.

Sites must report metrics on patient recruitment and accrual in trials. The program aims to develop knowledge at various levels to enhance access to regenerative medicine. Proposals should detail evaluation methods and culturally appropriate dissemination of findings.

For information about this program announcement, send email correspondence to:

Ccce@cirm.ca.gov



INFR 8: CIRM Community Care Centers of Excellence (CCCEs)