



Funding Opportunity Concept Plan

Alpha Clinics Network

Expansion

BACKGROUND

The mission of the California Institute for Regenerative Medicine (CIRM) is to *accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world*. To support this mission, CIRM created the Alpha Clinics Network to deliver high-quality FDA-authorized stem cell clinical trials to patients. Network sites at University of California Davis, University of California San Francisco, University of California San Diego, City of Hope, University of California Los Angeles, and University of California Irvine have collectively delivered over one hundred clinical trials with over 750 patients enrolled.¹ These trials emanate from CIRM's funding pipeline as well as non-CIRM funded investigator and industry sponsored projects.²

In addition, the network has developed a number of systems to encourage and support diverse patient participation in the rapidly maturing regenerative medicine landscape.³ These systems include a coordinated intake system for evaluating sponsors needs and identifying appropriate sites, outreach and navigation capacities to support the needs of California's diverse patient population, an IRB Reliance Agreement to support accelerated trial initiation, and protocol-specific partnerships among sites to manage GMP compliant processing of cell and gene therapy products.

¹ As of October 2020.

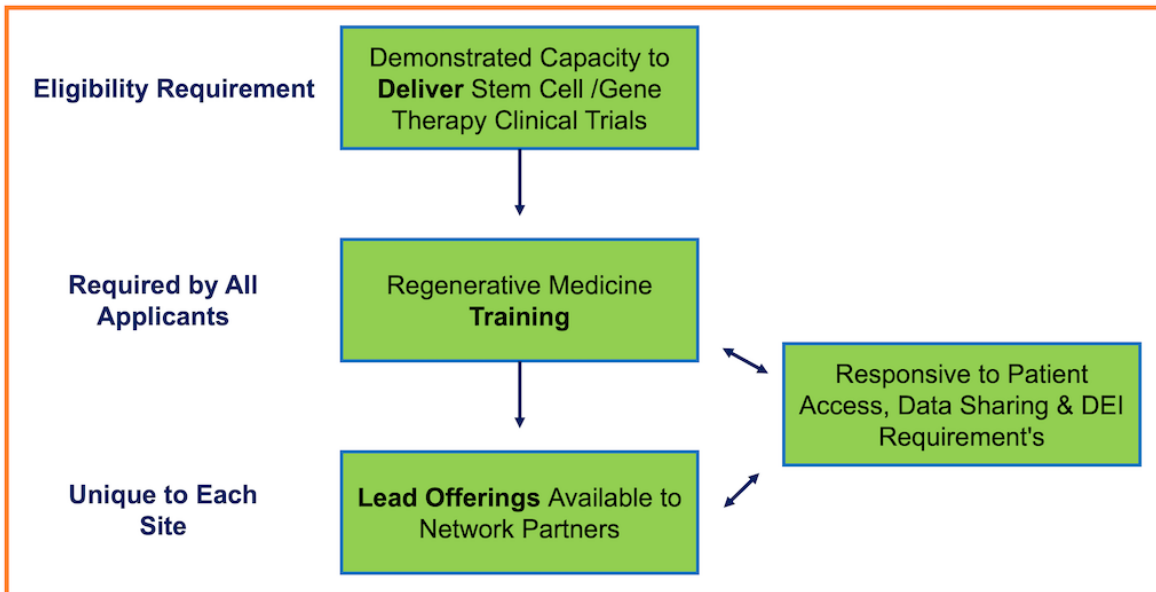
² <https://www.cirm.ca.gov/patients/alpha-clinics-network/alpha-clinics-trials>

³ <https://www.cell.com/action/showPdf?pii=S1934-5909%2818%2930225-X>

OBJECTIVE

The objective of this funding opportunity is expand existing capacities for delivering stem cell, gene therapies and other advanced treatment to patients. The Alpha Clinics Network is designed to serve as a competency hub for regenerative medicine clinical research and the delivery of approved treatments. Pursuant to this objective Alpha Clinics Network sites are expected to:

- ▶ Have a demonstrated ability to conduct FDA-authorized clinical trials involving cell and/or gene therapies
- ▶ Refine and expand network systems to address emerging issues or needs in the field of regenerative medicine
- ▶ Support the career development of physicians, nurses, research coordinators or other medical professionals integral to the delivery of regenerative medicine clinical trials
- ▶ Develop lead offerings (core capabilities or competencies) that can be utilized by other Alpha Network sites



AWARD INFORMATION

What activities will CIRM fund?

CIRM funds will support the following activities under this opportunity:

- Funds from this award shall be used to leverage existing assets within the medical center to support the objectives of the Alpha Clinics Network

CIRM funds cannot be used to support the following activities under this opportunity:

- Cost associated with the operation of individual clinical trials⁴
- Construction or renovation of physical facilities including equipment
- Activities already budgeted or paid for under a prior, existing or future CIRM award

What is the award amount and duration?

The CIRM Governing Board has allocated \$80 million to support the operation and enhancement of the Alpha Network within California. Each award will provide up to \$8.0 million in total funding over a five-year period.

Pursuant to Proposition 14, CIRM shall prioritize applications for Alpha Clinics Network and Community Care Centers of Excellence that offer matching funds or verified in-kind support, consistent with the highest medical standards, as established by the CIRM governing board.

How will funds be awarded?

Awards will be made in the form of a grant. CIRM will disburse funds pursuant to a Notice of Award (NOA) and based on operational milestones. Costs resulting from a delay or failure to meet an operational milestone will be the sole responsibility of the recipient. Successful applicants will have thoughtfully accounted for foreseeable project risks and developed contingency plans that do not require additional funding from CIRM.

ELIGIBILITY

What types of projects are eligible for funding?

To be eligible, the proposed project must satisfy the following requirements:

(1) Must be ready to initiate work on the funded project within 90 days of approval

Given the urgency of CIRM’s mission, all approved awardees must initiate work on the funded project within 90 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens’ Oversight Committee.

⁴ Clinical trial operating costs should be covered by the study sponsor. In the context of a CIRM-supported program such costs may be allocated in a Clinical Stage Program Award (e.g. CLIN2).

Because of the open and ongoing nature of this Program Announcement, investigators should only apply when their program has reached the stage where all eligibility criteria are met.

(2) Must have a California operating location

Only non-profit organizations are eligible to apply. At the time of the application deadline, the applicant organization must be located in California and must have the appropriate hospital/clinics and facilities accreditations and operational medical facilities in California. If these requirements are not met, CIRM may terminate all further action on the application.

(3) Must have demonstrated ability to perform stem cell or gene therapy clinical trials

The applicant organization must currently be conducting at least one clinical trial that meets the eligibility criteria for a CIRM Clinical Trial Stage Project. Applicants must identify two lead clinical trials that are active or would be initiated in 2022. The lead clinical trials must conform to the eligibility criteria for CIRM Clinical Trial Stage Projects Funding Opportunity (CLIN2).

(4) Must reside in an existing academic medical center with demonstrated capacity to conduct clinical trials

Applicants must be located within an academic medical center, licensed by the California Department of Public Health, that is currently performing regulated clinical trials registered on ClinicalTrials.gov. The medical center should consist of the necessary facilities and infrastructure to successfully implement stem cell clinical trials that meet the eligibility criteria for a CIRM Clinical Trial Stage Projects.

(5) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(6) Applicant must be in “good standing”

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

- a. Organizations in existence for less than five years:
 - (i) The applicant’s Chief Executive Officer, Chief Financial Officer, and Program Director must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and

(ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.

b. All Applicants:

The Program Director or key personnel must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by HHS Office of Research Integrity.

Who can apply?

California Organizations

California Organizations may use CIRM funds for eligible project costs incurred both in California and outside California. To qualify as a California organization, the organization must have >50% of its employees located in, and paid in, the state of California, and must direct and control the award activities from the California location.

Who can serve as the Program Director (PD)?

To be eligible, the PD must satisfy the following requirements:

- Must be an employee of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract
- Must have an active California medical license and hospital privileges at the applicant institution's medical center.
- Must propose a level of effort on the project consistent with achieving the project's aims and not less than 30% on average over the project period (note: "project" includes both the CIRM-funded and applicant co-funded components). Any effort for which salary from CIRM is claimed must be expended in California.
- Must be authorized by the applicant organization to conduct the research and assume the responsibilities of the PD.
- Must not currently have another application pending review or approval under this funding opportunity.
- Must not currently have another application that is substantially similar or has overlapping activities pending review or approval under any CIRM opportunity.

Addressing the Needs of Underserved Communities in CIRM-Funded Projects

All applicants for the Alpha Clinics Network Expansion program will be required to provide a statement describing:

1. How their Alpha Clinics Network site will support and facilitate outreach and study participation by underserved and disproportionately affected populations in the clinical trials they serve.
2. How the assembled Alpha Clinics Network site team will bring diverse and inclusive perspectives and experience to the implementation of proposed activities.
3. How well the research team demonstrates a successful track record for promoting and valuing diversity, equity and inclusion (DEI).

Knowledge Sharing Plan

Knowledge sharing has contributed to the success of the Alpha Clinics Network and is vital to advancing the field of regenerative medicine. Data or Knowledge Sharing Plans are required in all CIRM awards. Such plans include the collection, curation and preservation of data resulting from the conduct of the award. In the context of the Alpha Clinics Network award, applicants should develop plans intended to capture operational information vital to evaluating or replicating the (1) clinic's core competencies, (2) training programs and (3) lead offerings. Applicants should propose how this information can be made available to Network partners and the broader scientific community.

Applicants should describe their experience, resources and capacities to support data collection and for integration with established platforms such as registries, repositories, or other platforms in accordance with system standards such as the FAIR Principles of findable, assessable, interoperable and reusable data. CIRM expects applicants to facilitate sharing of knowledge to maximize the real world impact of CIRM-funded programs. Thus, the sharing plan may include the ability to support other awardees utilizing the Alpha Clinic in meeting CIRM data sharing requirements (e.g. Clinical Stage Program Awards)

A 5-year strategic CIRM goal is to build knowledge networks that foster and advance novel research approaches to generate a healthy culture of team science. Applicants should describe how their proposed Alpha Clinic will contribute to this strategic goal. Applicants are encouraged to allocate funds in their proposed budget for personnel and/or activities related to managing and sharing knowledge.

Organizational Integration Plan

In the application proposal, individual sites will be expected to describe, in the form of a Business and Organizational Integration plan, how they aim to leverage their capabilities so they become integral to clinical operations beyond the award period. In addition, the plan should describe operational synergies between the Alpha Network site and other CIRM Infrastructure and Research Programs. For example, the plan may discuss how proposed offerings may be supported by budgets from clinical trial awards or contracts.

SCHEDULE AND DEADLINES

Applications Due	April 2022
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Must start within 90 days of award approval (i.e., approximately 175 days post submission)