

Alpha Clinics Network Concept Plan



Geoffrey Lomax Dr.PH
Senior Officer
glomax@cirm.ca.gov



OUR MISSION

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



Program Metrics to Date

- \$40 million investment in patient-centered cell and gene therapy clinical research
- Resulting in over 105 clinical trials since 2015
 - 82 from industry and academic sponsors
 - 23 CIRM-funded academic or industry sponsored (CLIN2 awards)
 - 15 open at multiple Network sites
- Over \$95 million in industry contracts
- 11 trainees in MD Fellowship Program

Enable Innovative Clinical Research

Increase Patient Access to Therapies

Train Future Workforce



VIEWS



PROCEEDINGS OF
THE CALIFORNIA
STEM CELL AGENCY

Proceedings: Accelerating Stem Cell Treatments for Patients: The Value of Networks and Collaboration

GEOFFREY P. LOMAX, JOHN ADAMS, CATRIONA JAMIESON, JOHN ZAIA, MARIA T. MILLAN

California Institute for Regenerative Medicine, San Francisco, California, USA



PERSPECTIVES

Role of Nursing Competencies for Accelerating Clinical Trials in Stem Cell Clinics

MARY PERRIN,^{a,b*} TERESA KIM,^{a,b*} RODICA STAN,^{a,c} PAMELA GIESIE,^{a,b} JASON TABOR,^{a,b} VIRGINIA LE VERCHE,^{a,c} SHIRLEY JOHNSON,^{a,b} GEOFFREY P. LOMAX,^d JOHN A. ZAIA^{a,c}

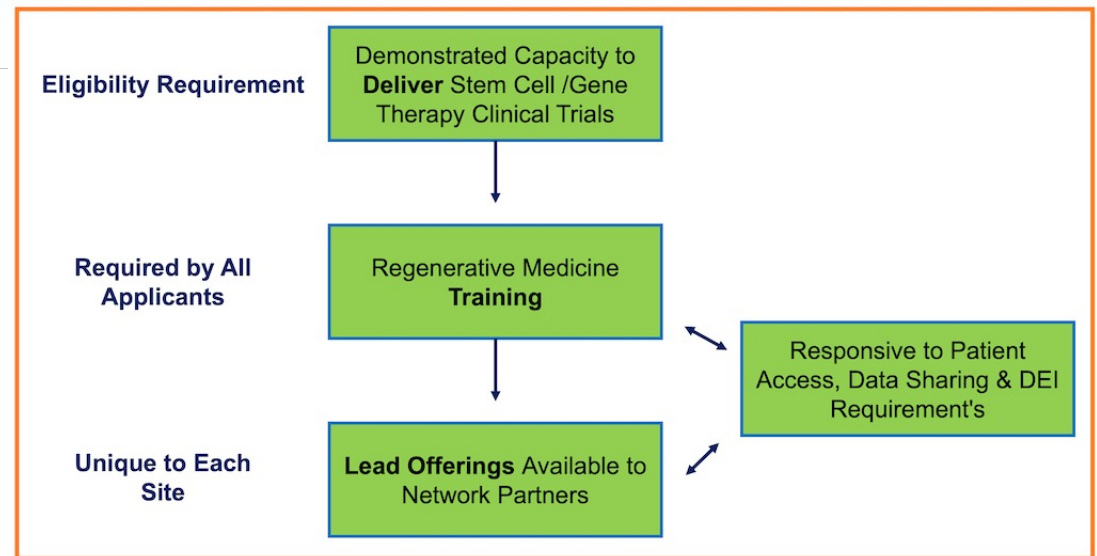
Cell Stem Cell
Forum

CellPress

CIRM Alpha Stem Cell Clinics: Collaboratively Addressing Regenerative Medicine Challenges

Catriona H.M. Jamieson,^{1,*} Maria T. Millan,² Abba A. Creasey,² Geoff Lomax,² Mary E. Donohoe,¹ Mark C. Walters,³ Mehrdad Abedi,⁴ Daniela A. Bota,⁵ John A. Zaia,⁶ and John S. Adams⁷

- \$80 million budget
- Open to California medical centers
- \$8 million maximum award amount for 5 years
- Priority given to applications that offer matching funds or in-kind support (Proposition 14)
- Combination of required and unique offerings



- Awards primarily fund teams to provide cell and gene therapy expertise across clinical units
- Teams support unique aspects of regenerative medicine trials including:
 - Apheresis and patient treatment
 - Product processing, biospecimen management and pharmacy
 - Regulatory support
- Clinical research coordination
- Training platform for the above activities





- ***Advanced Regenerative Medicine Research Platforms:***
 - Novel clinical trial design
 - Clinical research consortia
 - Genomic services / enhance precision medicine and patient centered care
 - Application of clinical tools and devices to deliver treatments in clinical trials
 - Data analysis tools and services
- ***Advanced Therapy Development:***
 - Platforms for accelerating the delivery of cell and gene therapies
 - Systems to support point-of-care manufacturing
- ***Access & Inclusivity:***
 - Registries and information systems or platforms to support access, navigation, RWE and PRO
 - Proposals to advance access and delivery including underserved populations

- Sites may propose partnerships among different Alpha Clinics to support lead offerings
- Plans should include MOUs among partner sites and contingency plans in the event one or more sites not funded
- Sites encouraged to discuss how they have partnered with non-academic medical centers and discuss potential for clinical research partnership



- Applicants expected to describe, in the form of a Business and Organizational Integration plan, how they aim to leverage proposed capabilities, so they become integral to the center's operations beyond the award period.
- Plans should be revised over the award period
- In addition, the plan may describe operational synergies between the Alpha Network site and other CIRM programs.



INFR 4: Alpha Clinics Network Expansion Award

The Alpha Clinics Network Expansion Award aims to 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 training, clinical research, and the delivery of approved treatments.

Please see the RFA for full details:

- [INFR 4 RFA: Alpha Clinics Network Expansion Award \[pdf\] \(03.08.22\)](#)

An [FAQ](#), which will be periodically updated in response to ongoing questions received by CIRM, and [tips on the application WYSIWYG editor](#) are available.

- 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.
- Describe your 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)

What activities will CIRM not fund?

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

- ✘ Activities already covered by a prior, existing, or future CIRM award, i.e., budgetary overlap
- ✘ Construction or renovation of physical facilities including equipment
- ✘ Cost associated with the operation of individual clinical trials⁸

Equipment is non-expendable, free-standing, tangible personal property with a normal life expectancy of one year or more and an acquisition cost which equals or exceeds the lesser of the capitalization level established by the Grantee for financial management purposes or \$5,000.

- Create operational and programmatic linkages to CIRM CLIN 1 and 2 programs
- Propose novel core competencies that address the technical aspects of cell/gene therapy delivery
- Leverage and expand your existing capacities
- Offer focused and innovative solutions to the challenges of enrollment/outreach for rare/ultra-rare clinical trials
- Contact us if you have questions

- Please use the "raise hand" button to be recognized

