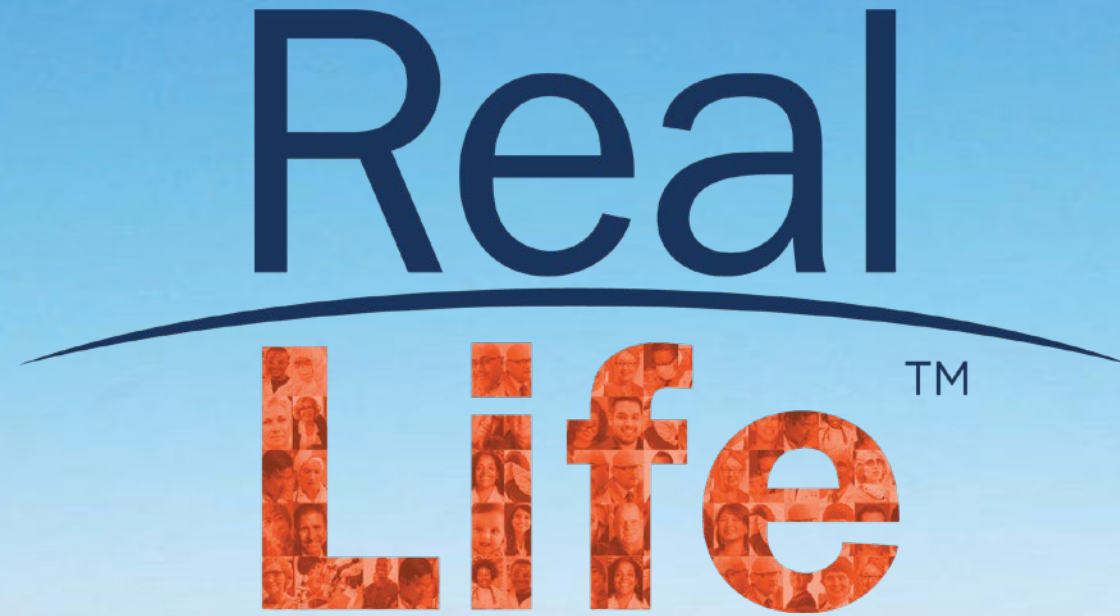


Alpha Clinics Network Concept Plan



Geoffrey Lomax Dr.PH

Senior Officer

January 2022 ICOC Meeting

January 27, 2022



OUR MISSION

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



Core Capacities

- Provide advanced stem cell and gene therapy clinical research infrastructure
- Dedicated to patient-centered care
- Support CIRM's workforce training and community outreach objectives
- Accelerate CIRM's cell and gene-therapy clinical pipeline programs and trials



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 (UC Davis and UC San Francisco)

**Enable Innovative Clinical
Research**

**Increase Patient Access to
Therapies**

Train Future Workforce

- Common intake process for sponsors
- Cohort identification tools leveraging CTSA patient registries
- IRB Reliance Agreement to accelerate multi-site trials
- Rapid approval of compassionate use protocols
- Collaborative treatment protocols between multiple sites
- Knowledge sharing in regulatory and operational aspects of regenerative medicine





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

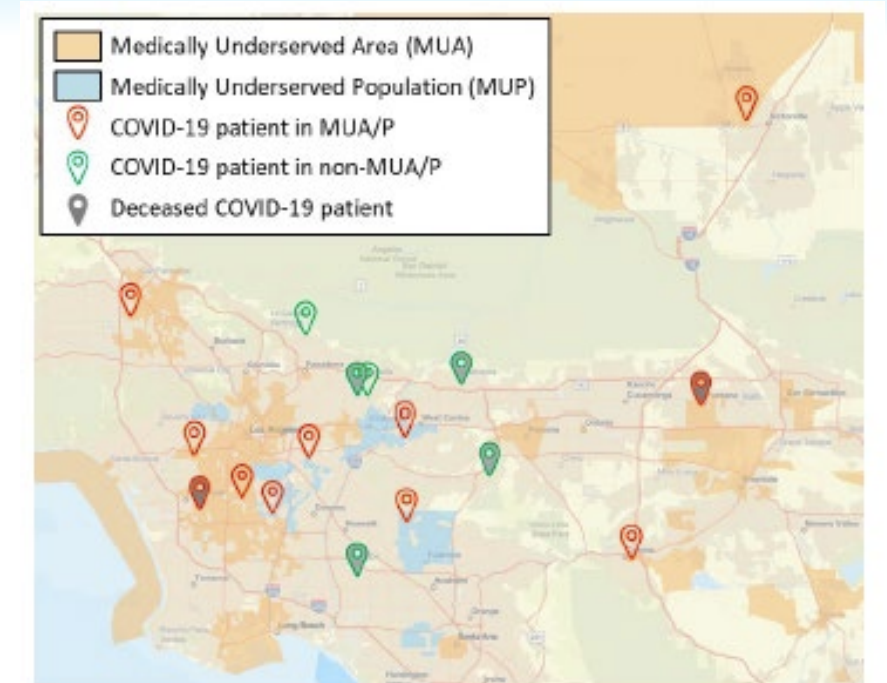
CellPress

CIRM Alpha Stem Cell Clinics: Collaboratively Addressing Regenerative Medicine Challenges

Catrina 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

Use Case Medically Underserved Areas/Populations

- Determined to be a critical demographic to include in antibody analysis of convalescent COVID-19 patients
- COH, UCI and UCSD collaborate to expand recruitment
- Sites utilized census data to identify COVID patients residing in MUA/Ps (zip code level)
- A variety of recruitment strategies employed to attract diverse donor population from these areas
- 76 (44%) of the 172 study donors lived in MUA/P
- Demonstrates how Network can deploy tools combining medical and demographic data to support diversity



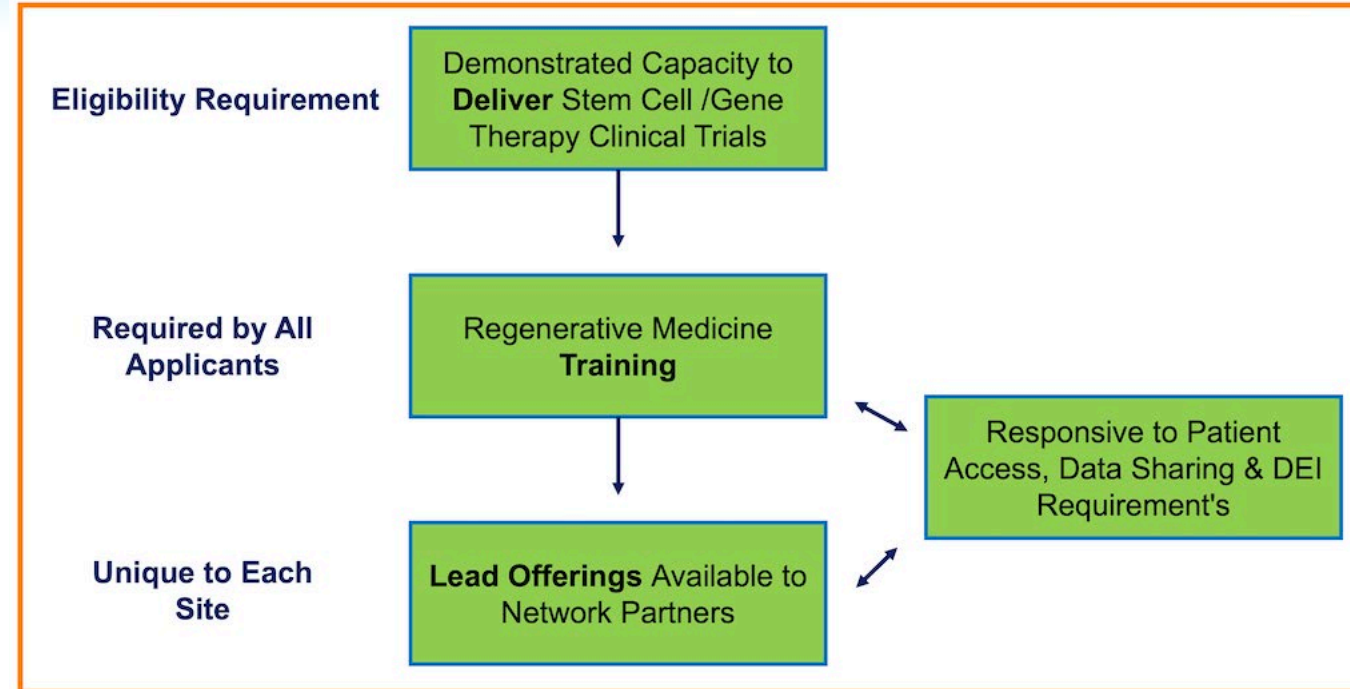
- Awards primarily fund teams to provide cell and gene therapy expertise across clinical units
- Teams support unique aspects of regenerative medicine trials including:
 - Apheresis and patient treatment
 - Product processing, biospecimen management and pharmacy
 - Regulatory support
- Clinical research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



- Expand expertise and capacity as the field of regenerative medicine expands
- Continue to develop the workforce in size and diversity to address gaps and growing number of regenerative medicine clinical trials
- Serve as clinical competency hubs to support the statewide development of patient care capacity
- Address the diverse needs of California patients



- \$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





- ***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

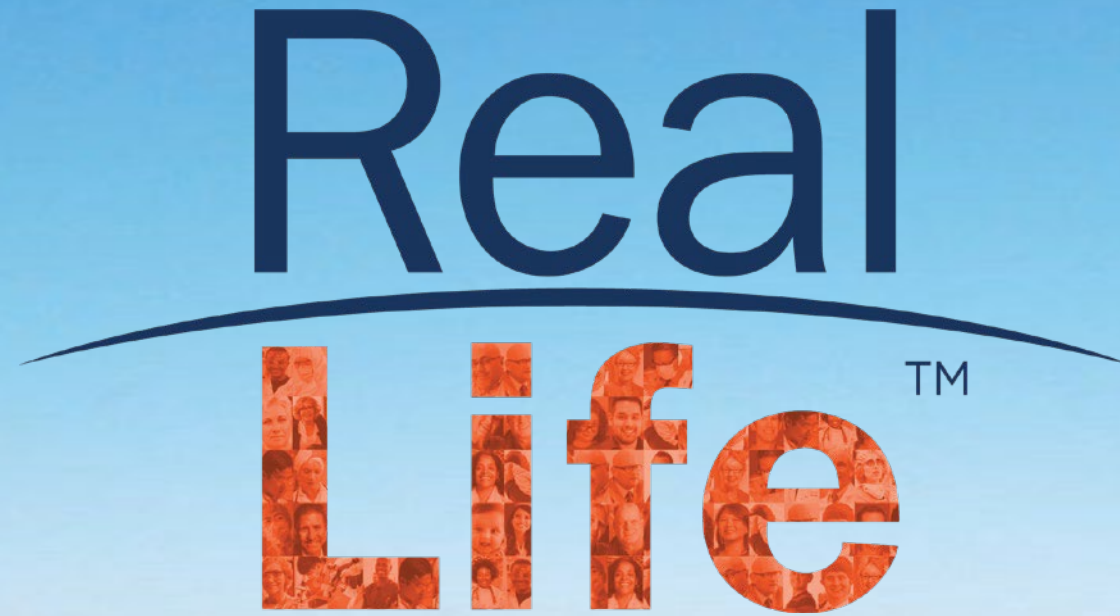
- Sites may propose partnerships among different Alpha Clinics to support lead offerings
- Plans should include MOUs among partner sites and contingency plans in the event one or more sites not funded
- Sites encouraged to discuss how they have partnered with non-academic medical centers and discuss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



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