



**Gil Sambrano, PhD**

Vice President Portfolio Development and Review

Portfolio Development and Review

GWG Alpha Clinics Review Recommendations

October 27, 2022

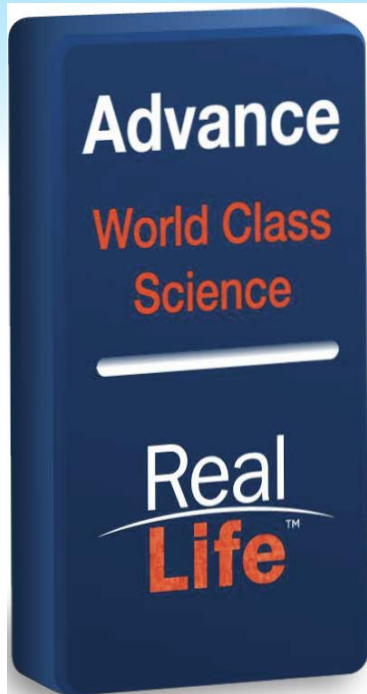


## OUR MISSION

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



# Prop 14-Era: Our 5-Year Strategic Plan



- Develop shared resources
- Build knowledge networks



- Advance therapies to marketing approval
- Create a manufacturing partnership network
- **Expand Alpha Clinics Network**
- Create Community Care Centers of Excellence



- Build a diverse and highly skilled workforce
- Deliver a roadmap for access and affordability



# Alpha Clinics Network: Making Clinical Trials Accessible to Many



- Currently supporting 6 Alpha Clinics sites
- \$40M investment in patient-centered care and training
- Successfully accelerating cell and gene-therapy clinical trials
- Over 105 trials supported since 2015
  - 82 from industry sponsors
  - 23 CIRM-funded industry and academic sponsors
- Over \$100M in industry-contracts

# In Development: Increase Access & Engage the Community

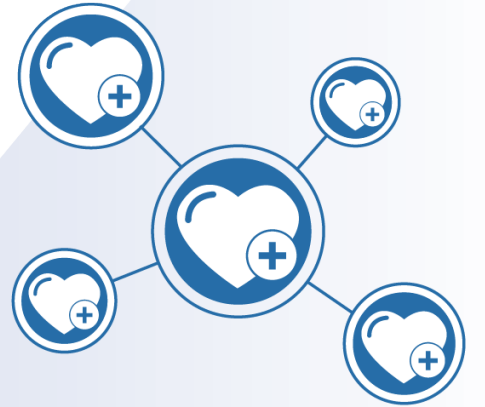


Expand Alpha  
Clinics  
Network

Enable Innovative  
Clinical Research

Increase Patient Access  
to Therapies

Train Future Workforce



Equip Community Care  
Centers to serve the  
needs of the community  
as identified by the com-  
munity

To expand\* existing capacities for delivering stem cell, gene therapies and other advanced treatment to patients.

To serve as a competency hub for regenerative medicine training, clinical research, and the delivery of approved treatments.

\*Expansion may include establishing additional Alpha Clinics sites and/or expanding the services and reach of existing Alpha Clinics sites.

- **Clinical Trials:** Have a demonstrated ability to conduct FDA-authorized clinical trials involving cell and/or gene therapies
- **Network Coordination:** Refine and expand Network systems to address emerging issues or needs in the field of regenerative medicine
- **Regenerative Medicine Training:** Support the career development of physicians, nurses, research coordinators or other medical professionals that are integral to the delivery of regenerative medicine clinical trials
- **Expanded Network Capabilities/Lead Offerings:** Develop lead offerings (core capabilities or competencies) that can be utilized by other Alpha Clinic Network sites

## Applicants may propose to focus on a few or broadly address several offerings such as:

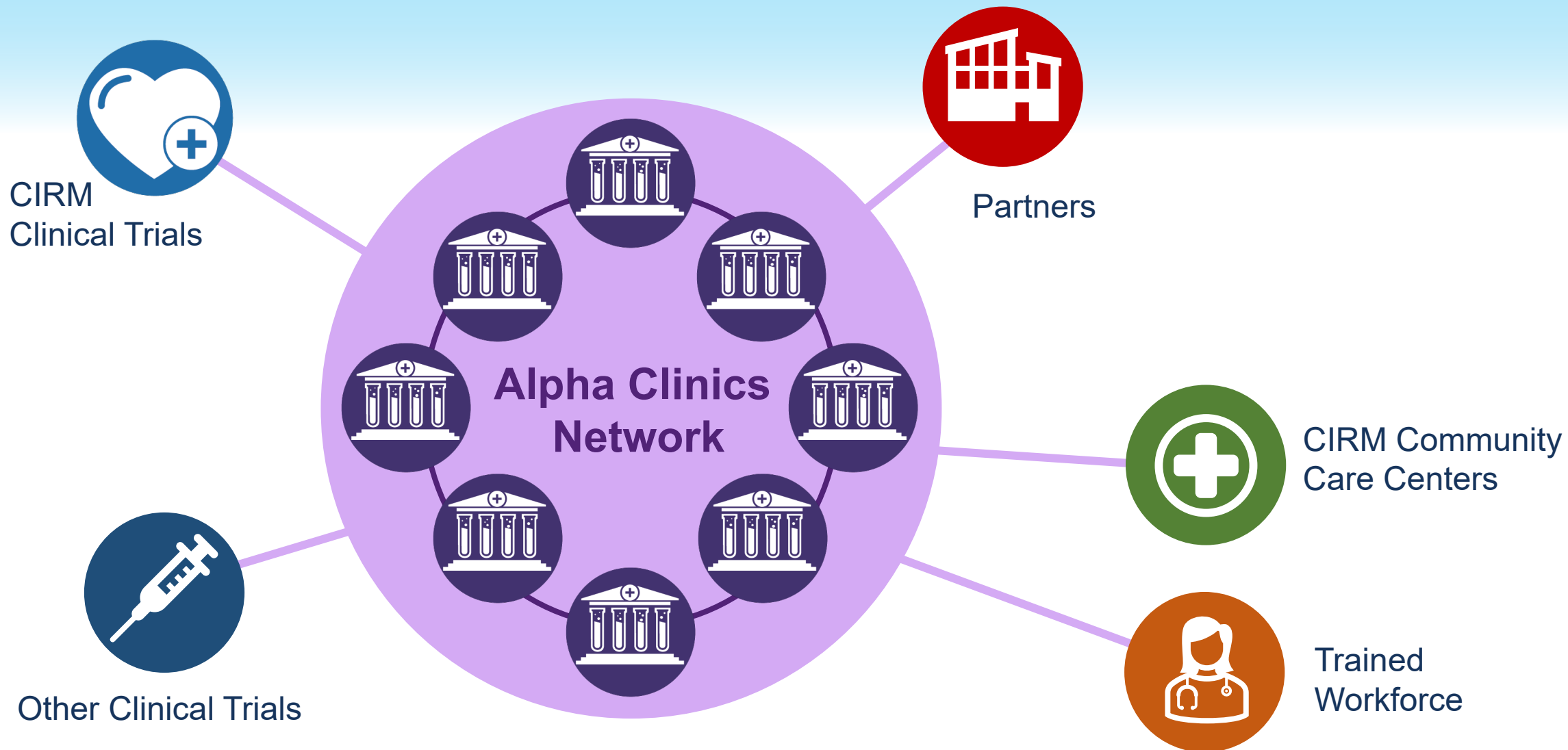
- Develop novel clinical trial designs (e.g., basket trials, umbrella trials)
- Provide tissue banking or genomics services
- Develop and/or provide tools, devices or technologies (e.g., imaging to assess engraftment or specialized device for cell delivery)
- Provide or develop programs for decentralized point of care treatments
- Develop data and information platforms to support knowledge sharing
- Provide patient navigation tools or other activities that promote access and inclusivity
- Increase the participation of underserved populations in clinical research
- Other offerings we haven't thought of...



- **Partnerships:** Applicants may propose partnerships with other Alpha Clinic sites, or other organizations such as potential Community Care Centers to support their offerings and capabilities.
- **Business and Organizational Integration Plan:** Applicants should provide a plan for how they will leverage their capabilities, so they become integral to clinical operations of the organization beyond the award period. The plan should also address how the applicants would maximize access to patients, sponsors and other network partners.
- **Knowledge Sharing:** Applicants should describe how they will facilitate data sharing for both the clinical trials they serve as well as their own operations (e.g., best practices, replicating a core competency)

## Must Include Plans to Address DEI

- Alpha Clinics Network sites should support and facilitate outreach and study participation by underserved and disproportionately affected populations in the clinical trials they serve.
- Alpha Clinics Network sites should propose ways to bring diverse and inclusive perspectives and experience to the implementation of proposed activities



- The CIRM Board has allocated up to \$80M to support this funding opportunity
- Each award provides up to \$8M for 5 years
- 9 applications were submitted and accepted for review
  - 6 existing sites
  - 3 new sites

- **Score of “1”**

*Exceptional merit and warrants funding.*

*May have minor recommendations and adjustments that do not require further review by the GWG*

- **Score of “2”**

*Needs improvement and does not warrant funding at this time but, at the applicant's option, may be resubmitted to address areas for improvement if the Application Review Subcommittee has not approved an application for funding following the Grants Working Group's review.*

*GWG recommendation to revise and resubmit application. ARS may choose to fund, not fund, or have GWG re-evaluate revisions*

- **Score of “3”**

*Sufficiently flawed that it does not warrant funding.*

Applications are scored by all scientific members of the GWG with no conflict.



# Scientific Review Criteria

## Basis for Scientific Score

1. Does the proposal offer a significant value proposition that would enhance the ability of the Alpha Clinics Network to accelerate clinical research consistent with CIRM's mission?
2. Is the proposal well planned and designed to successfully implement the Alpha Clinic core activities, regenerative medicine training, expanded capabilities and lead offerings?
3. Is the proposal feasible?
4. Will the proposed Alpha Clinic effectively serve the needs of underserved and disproportionately affected communities?

Priority will be given to applications that offer matching funds or verified in-kind support

- Initial discussion ~ 20 minutes
- Applicant Presentation “Pitch” – 10 minutes
- Q&A with Applicant – 10 minutes
- Wrap-up discussion and scoring ~ 15-20 minutes
  - Repeat for each application

	Number of Apps	Total Applicant Request	Funds Available
<b>Recommended for funding</b> Score of “1”	8	\$63,949,539	\$80,000,000
<b>Recommended for revision</b> Score of “2”	1	\$8,000,000	
<b>Not recommended for funding</b> Score of “3”	0		

For each award, the final award amount shall not exceed the amount approved by the ICOC Application Review Subcommittee and may be reduced contingent on CIRM’s assessment of allowable costs and activities.

- Under Prop 14, any application that is not recommended for funding by the GWG, but which had 35% or more members score to fund the application must include a minority report.
- The minority report is included in the review summary and provides a brief synopsis of the opinion of reviewers that scored the application 85 or above.

Score	Votes for Score of "1"	Votes for Score of "2"	Votes for Score of "3"	Funds Requested
2	6	8	0	\$8,000,000

- Quality team with well-established expertise in stem cell biology and regenerative medicine
- Strong clinical trial management and the capacity to deliver systems that may benefit the network
- Support for a broad scope of regenerative medicine projects would ultimately be more likely to further CIRM goals and benefit California citizens
- Offers significant matching/in kind funds



CIRM Team concurs with the GWG recommendations for funding.

In addition, the CIRM Team supports the minority position for application INFR4-13597 and recommends funding of this application.

- *The institute shall prioritize applications for Alpha Stem Cell Clinics 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 governing board of the institute.*
- *The institute shall prioritize the funding of applications for Community Care Centers of Excellence that enhance the geographic distribution of Community Care Centers of Excellence across the state, considering the location of the Alpha Stem Cell Clinics, to promote patient access.*

Board members with Conflicts of Interest for INFR 4 applications	
Haifaa Abdulhaq	Pat Levitt
Kim Barrett	Linda Malkas
Michael Botchan	Shlomo Melmed
Linda Boxer	Christine Miaskowski
Deborah Deas	Suzanne Sandmeyer
Ysabel Duron	Barry Selick
Leon Fine	Michael Stamos
Elena Flowers	Art Torres
Judy Gasson	Karol Watson
Larry Goldstein	Keith Yamamoto
Jim Kovach	