

Community Care Centers of Excellence (INFR8) FWG and GWG Recommendations



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Portfolio Development and Review

Our Mission

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



SAF | CIRM's Impact Goals

Accelerating Discovery & Translation

1. **Catalyze** the identification and validation of at least 4 novel targets and biomarkers, ensuring integration into preclinical or clinical research for diseases in California
2. **Accelerate** development and utilization of 5-8 technologies that have the potential to improve safety, efficacy, and/or quality of cell and gene therapies

Cell & Gene Therapy Approvals

3. **Advance** 4-7 rare disease projects to BLA
4. **Propel** 15-20 therapies targeting diseases affecting Californians to late-stage trials

Accessibility & Affordability of CIRM-Funded Cell & Gene Therapies

5. **Ensure** that every BLA-ready program has a strategy for access and affordability

Diverse Workforce Development

6. **Bolster** CIRM's workforce development programs to address gaps and meet evolving demands in regenerative medicine

CCCE Targets Access and Workforce Recommendations

Goal 5 - Ensure that every BLA ready program has a strategy for access and affordability



Strengthen Clinical Infrastructure Connectivity

- Build interconnectivity & performance metrics between CIRM Clinical Infrastructure (Alpha Clinics, CCCEs, PSPs) to ensure enhanced **referral, enrollment, & retention** of California patients in clinical trials

Goal 6 - Bolster CIRM's workforce development programs to address gaps and meet evolving demands in regenerative medicine



Launch Outreach Campaigns to Educate the Public & Increase Diversity of California's Regenerative Medicine Workforce

- Develop programming to support outreach/education efforts for K-12, teachers, & community members via collaboration with key stakeholders.

Infrastructure



CCCE Program Objectives

Expand clinical research centers of excellence across California to enhance patient access to regenerative medicine treatments by:

1. Expanding the geographic reach of centers capable of delivering clinical trials and approved therapies
2. Developing a skilled workforce to support the delivery of regenerative medicine treatments and ensure broad accessibility to California patients.

Infrastructure



CCCE Program Scope

- Initiate clinical trial agreements or contracts with sponsors for the delivery of approved products.
- Develop operations and management systems to perform regenerative medicine clinical trials or deliver approved products in the CCCE setting including manufacturing, processing, and delivery.
- Enroll and provide coordinated care to patients in clinical trials or the delivery of approved products.
- Cohort Identification, outreach and engagement
- Patient Navigation
- Clinical Research Support (screening, follow up/monitoring, outcomes including real world evidence)
- Career Development
- Partner with community-based organizations to reduce disparities and support broad representation in trials (\$650K min)
- Knowledge Sharing
- Facility Renovation allowed, but not required

Infrastructure



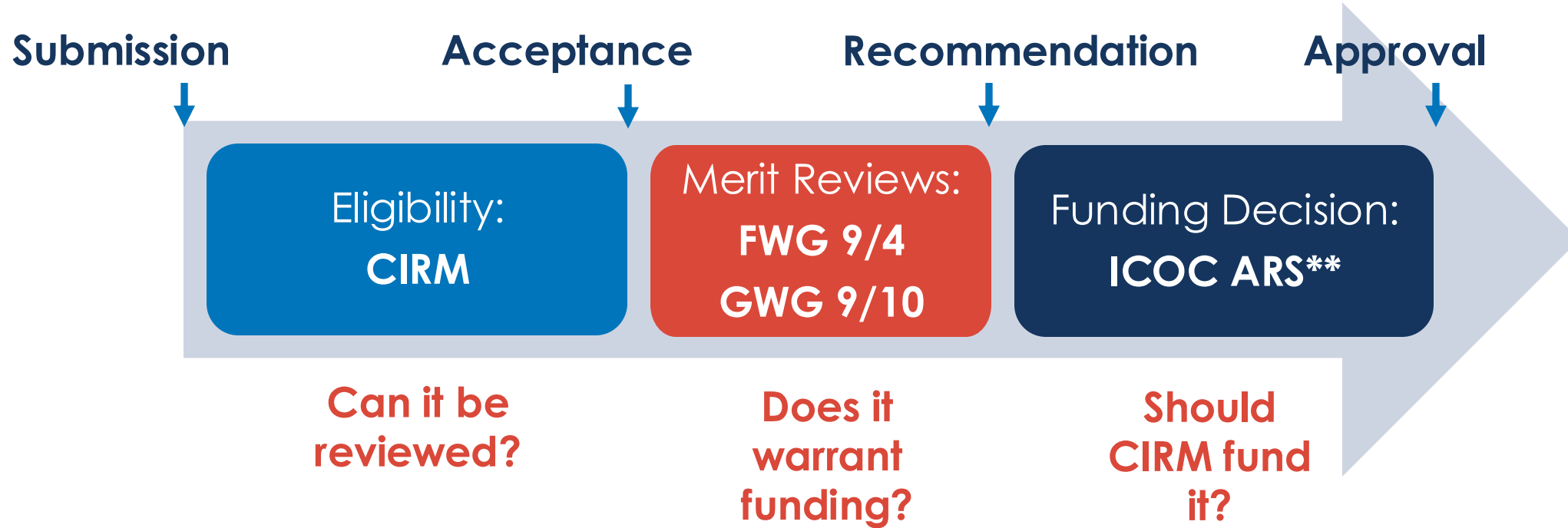
CCCE Program Structure

Scope	Conduct FDA-authorized clinical trials involving stem cell-based or genetic regenerative medicine therapies, make approved regenerative medicine treatments broadly available to California patients, and develop the regenerative medicine workforce.
Applicant Eligibility	CA nonprofits with a demonstrated ability to perform clinical trials, no ASCC, must not offer fee for service “stem cell therapies”
PD Eligibility	Minimum 30% effort commitment
Allocation	\$36M CCCE program \$9M maximum/award
Duration	5 years

Infrastructure



CCCE Review Process



** Independent Citizens' Oversight Committee, Application Review Subcommittee

Infrastructure



CCCE Scoring System

Median Score 85-100: *Exceptional merit and warrants funding.* May have minor recommendations and adjustments that do not require further review by the GWG

Median Score 1-84: *Sufficiently flawed that it does not warrant funding. Resubmission is not planned for this opportunity.*

Infrastructure



CCCE GWG Review Criteria

1. **Value Proposition** - *To what extent does the proposed center offer an impactful and practical value proposition for patients, trial sponsors and/or health care providers?*
2. **Plan and Design** - *Are the clinical operations appropriately planned and designed to expand the accessibility of regenerative medicine treatments?*
3. **Feasibility**- *How feasible is the project plan, and how likely is it to be implemented within the proposed timeline?*
4. **Serving the needs of California Patients and Affected Communities** - *To what extent do the proposed activities hold the potential to increase referrals or patient access*

Special Consideration: pursuant to Proposition 14, CIRM shall prioritize applications for CCCE that offer matching funds or verified in-kind support, consistent with the highest medical standards, as established by the CIRM governing board. Matching funds, if proposed, should be documented in the letters of support.

Infrastructure



CCCE FWG Review Criteria

- 1. Appropriateness of the renovation and facilities improvement project to support the proposed CCCE activities-** *To what extent does the scope of work, as defined by the facilities design narrative, plans, and other relevant information, describe a facility that best supports the goals of the proposed CCCE? Is the proposed location and layout of the facility appropriate for its goals?*
- 2. Feasibility of the proposed renovations/facility improvements -** *To what extent is the proposed construction timeline, including key milestones and activity timelines, feasible and appropriate for the project? How well is the project staffed with appropriate levels of renovation/construction expertise?*
- 3. Appropriateness of the renovation/facility improvement costs** *To what extent do the proposed costs adequately account for design, construction, equipment, contingencies, and any other anticipated costs? Is the project appropriately budgeted to adhere to prevailing wage requirements?*

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Community Care Centers of Excellence (CCCE)

APP #	TOTAL BUDGET REQ	GWG SCORE	Hi	Lo	85 or >		FWG SCORE	Hi	Lo	85 or >		CIRM Recommendation
					Y	N				Y	N	
INFR8-18772	\$9,000,000	90	92	85	15	0	86	90	85	7	0	FUND
INFR8-18824	\$9,000,000	89	95	83	13	1	N/A	N/A	N/A	N/A		FUND
INFR8-18823	\$8,996,101	87	90	80	11	1	90	95	80	6	1	FUND
INFR8-18783	\$8,978,900	80	85	70	2	11	N/A	N/A	N/A	N/A		DO NOT FUND

Amount recommended: \$26,996,101

Amount available: \$36,000,000