

Community Care Centers of Excellence Concept Overview

March 10, 2025

CIRM Access and Affordability Working Group



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Program Mandate

Community Care Centers of Excellence are infrastructure described in Proposition 14.



Establish the Community Care Centers of Excellence Program to:

- *Expand the capacity of the Alpha Clinics*
- *Promote **access** to human clinical trials and the accessibility of treatments and cures arising from institute-funded research*
- *Establish **geographically diverse** centers of excellence to conduct clinical trials and to seek to make the resulting treatments and cures broadly available to California patients.*

Goal 5 | Recommendations

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

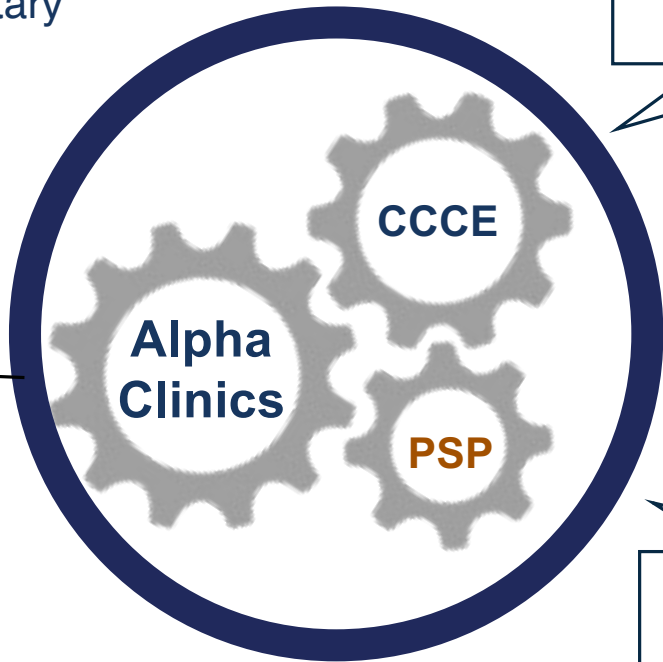
Strengthen Clinical Infrastructure Connectivity

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

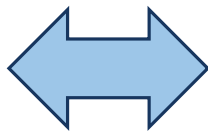
Objective of CIRM's Clinical Infrastructure

Building **interconnectivity**
between complementary
infrastructure

337 trials
(cumulative as
of 8/2024)



Need and opportunity to
expand delivery to
underserved areas



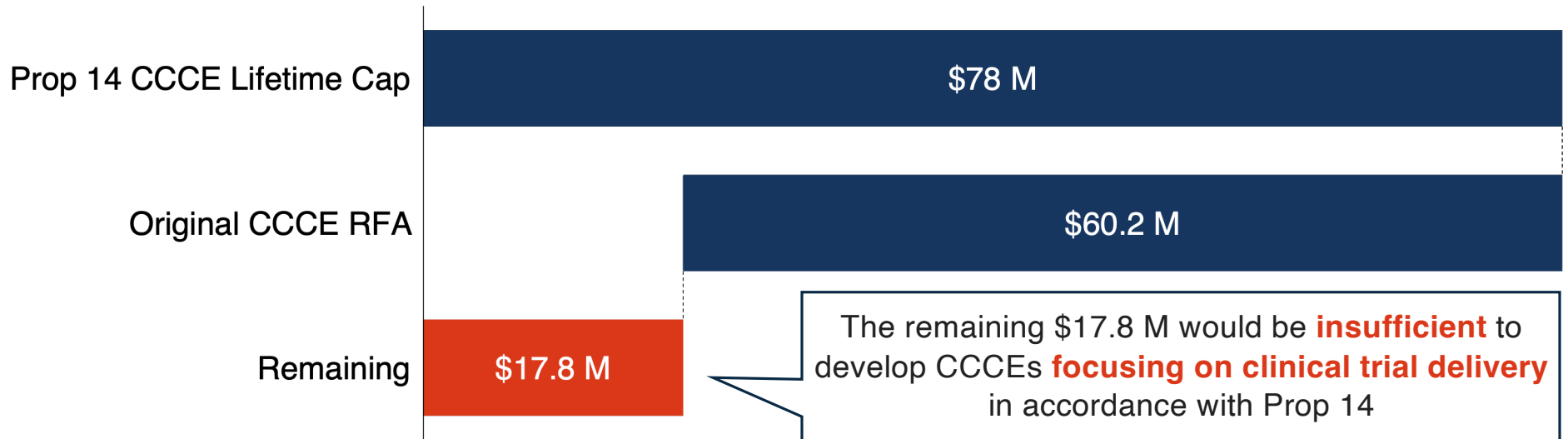
CLINICAL

Logistical and financial
support addressing
participation barriers

CCCE Initial Cycle

	CCCE INFR 8
Structure	1) a Support Site or (2) a Support and Delivery Site.
Applications Received	<ul style="list-style-type: none">• 9 Total<ul style="list-style-type: none">➤ 4 x Support Only Sites and➤ 5 x Support and Delivery Sites
GWG/FWG Outcome	<ul style="list-style-type: none">• 1 x Support Only Site - Funding recommendation• 8 x applications - Not recommended for funding

CCCE Budget considerations



- By **revising** the concept, we aim to provide a sustainable financial framework for both CCCEs and support-only activities

Key Insights from the First CCCE Round

- **Sustainability Concerns** – The initial funding structure would have exhausted nearly the entire CCCE budget in one cycle, leaving little for future awards or program expansion
- **Geographic Diversity Gaps** – While applications came from various areas, they didn't fully align with our goal of expanding access to underserved regions
- **Program Alignment with Proposition 14** – Applications didn't fully capture the integration of **clinical trial delivery** and **long-term patient support**, which are core to the CCCE vision
- **Need for comprehensive approach** to fully fund **delivery** and **support**

These considerations led us to refine the concept plan, ensuring a stronger, more sustainable, and more impactful approach

Transitioning to a Two-Phase Model

Refining: Two-Phase Approach for Sustainability

Category	2025	2026	2027	2028	2029	2030
CCCE Delivery	Delivery RFA*		First Cycle Sites Active			
				Delivery RFA	Second Cycle Sites Active	
AAWG Support		Support RFA		Support RFA		

Category	Funding Amount	Source
CCCE Delivery	\$78M (2 funding cycles)	Proposition 14 (earmarked for CCCEs)
AAWG Support	\$93M **	Patient Access & Affordability allocations

* "RFA" timeline includes RFA development, application review, and award contracting

** Available funding for patient access & affordability allocations – **NOT** all for support RFAs

CCCE Phase 1 - Concept

1. Objective
2. Structure
3. Eligibility
4. Timeline

Objective

Expand **geographically diverse** centers of excellence across California to enhance patient access to regenerative medicine treatments by:

- (1) **Expanding** the **reach** and **delivery** of clinical trials and approved therapies, and
- (2) Developing a **skilled workforce** to support the **delivery** of regenerative medicine treatments and ensure **broad accessibility**, particularly in **underserved communities**.

Award Structure

	CCCE INFR 8
Max Duration	5 years
Applicant	<ul style="list-style-type: none"> • CA non-profit or for-profit research institutions in good standing <ul style="list-style-type: none"> • Commitment to CGT treatment from any source • Organization does not have an INFR4 award • Only providing FDA-authorized treatments
Core Team	Program Director (30%)
Max Award	\$9 M (total cost capped)
Program Budget (FY25/26)	\$36,000,000

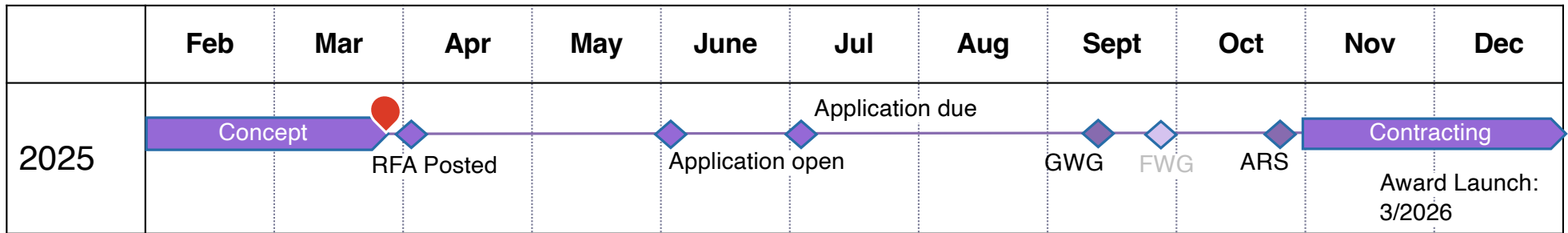
CCCE I Eligibility

	Eligibility Requirements
Applicant	<ul style="list-style-type: none"> • California Organization • Must not be currently funded under CIRM’s Alpha Clinics (INFR 4) Program
Expected Outcome	<ul style="list-style-type: none"> • Must have demonstrated ability to perform human clinical trials • Must have or propose to develop capability to deliver regenerative medicine clinical trials and approved products • Must propose at least one partnership with a community-based organization or organizations to support clinical research, career development, or engagement
Award Start	Must be ready to initiate work on the funded project within 120 days of award approval
Program Director (PD)	30% effort

BOLD: Update from initial concept plan

Concept Launch Timeline

Application to award start ~ 10 months
Awards start in March 2026



- Engage AAWG to consider funding opportunity for Support-Only activities

Request for Motion

We request a motion that the Access & Affordability Working Group recommend approval of the revised **CCCE Concept** to the full ICOC