

CIRM

CALIFORNIA INSTITUTE FOR
REGENERATIVE MEDICINE

Grants Working Group Recommendations

**INFR8 Community Care Centers of
Excellence**

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Agenda

- ① INFR8 Program Overview
- ② Review Process
- ③ Recommendations

INFR8 Program

INFR8 CCCE Program Objective

To expand clinical research centers of excellence across California to provide and enhance access to regenerative medicine treatments to patients.



INFR8 CCCE Program Contributes to These Impact Goals

Goal 5: 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

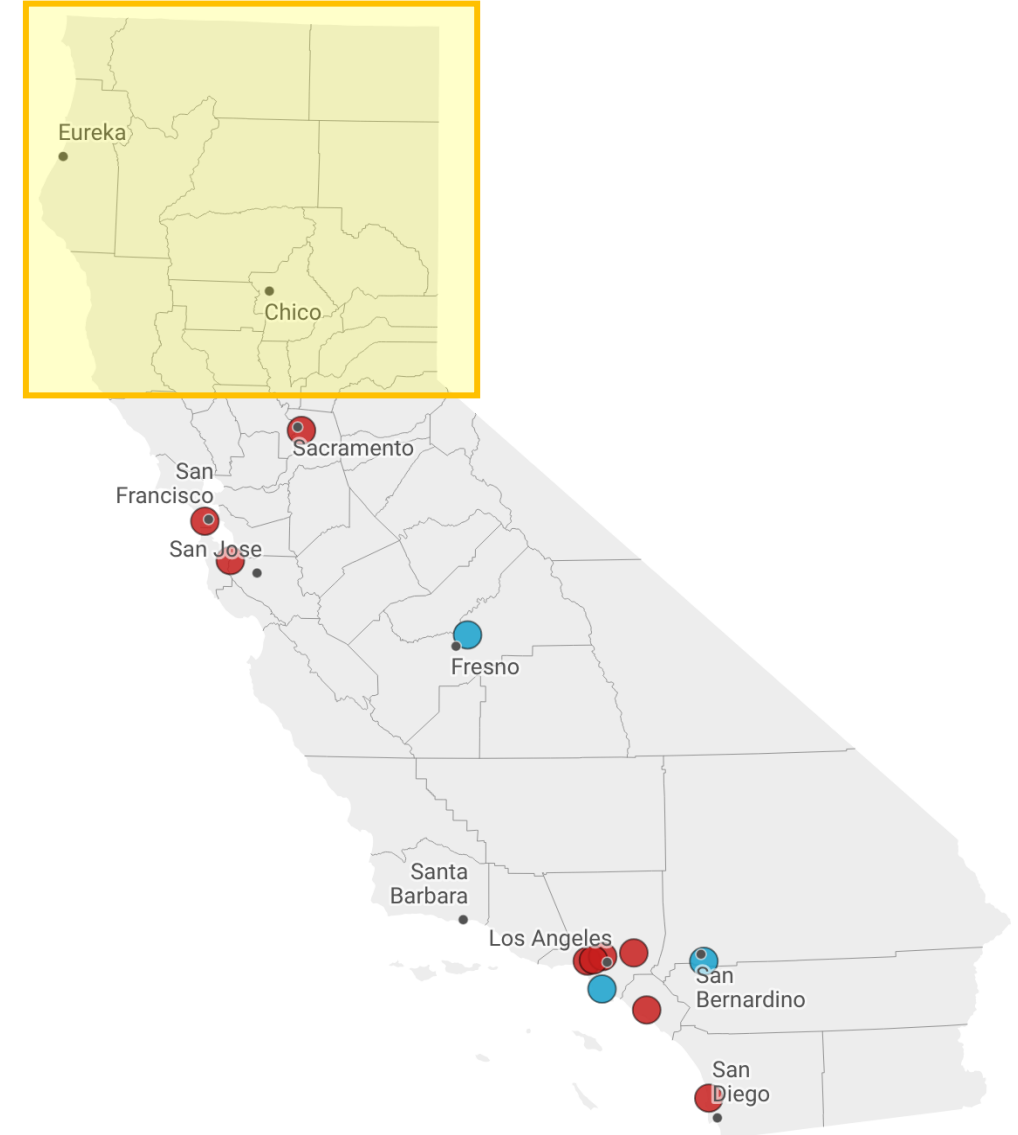
Geographic Gap Identified

- In October, ICOC expressed concerns that northern regions are not served by clinical infrastructure
- Total population of roughly 2.9 M people
- Directed CIRM to identify options to expand reach of CIRM's clinical infrastructure to northern CA

CIRM Clinical Infrastructure

Alpha Clinic

Community Care Center of Excellence

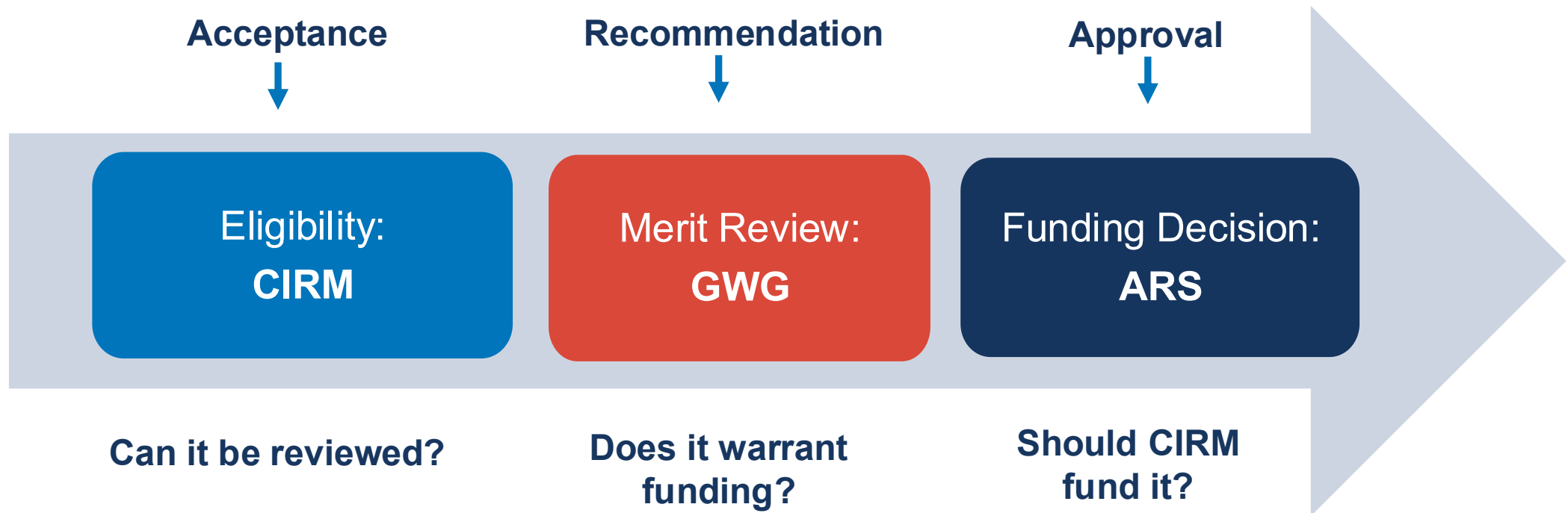


INFR8 CCCE Program Structure

	INFR8
Recurrence	Does not recur
Max Duration	5 years
Applicant	Organizations in designated counties of Northern California
Max Award (total cost)	\$9M
Awards	1
Allocation 2026	\$9M

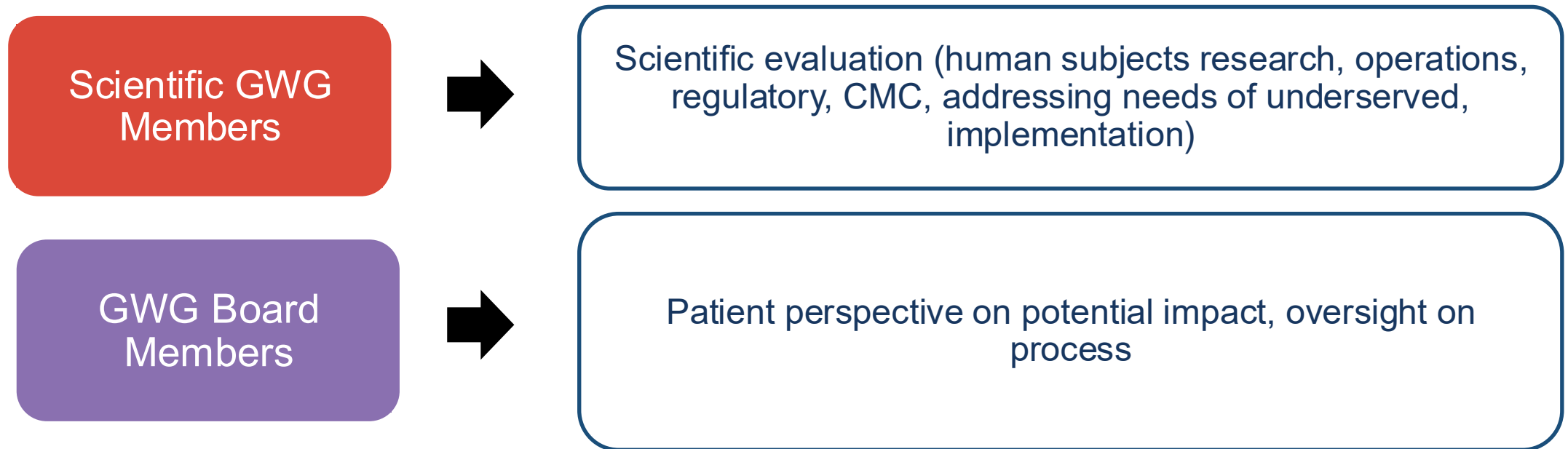
Review Process

INFR8 CCCE Application and Review Process



INFR8 CCCE GWG Panel Composition and Roles

Who participates and how they contribute



Scientific Scoring System

Using the 1 to 100 scale

- **Median score of 85-100:** Exceptional merit and warrants funding, if funds are available.
- **Median score of 1-84:** Not recommended for funding.
- Scoring is holistic and based upon all facets of the expert review.
- GWG are encouraged to make full use of the scoring range to signal their enthusiasm for each project.

INFR8 Scientific Review Criteria

- **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?
- **Plan and Design** - Are the clinical operations appropriately planned and designed to expand the accessibility of regenerative medicine treatments?
- **Feasibility** - How feasible is the project plan, and how likely is it to be implemented within the proposed timeline?
- **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?

Recommendations

GWG Recommendations

Recommendation	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding	1	\$9,000,000	\$9,000,000
Not recommended for funding	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.

CIRM Team Recommendations

The CIRM Team recommendation to the ARS:

- Fund the 1 application recommended by the GWG for a total amount of \$9,000,000.