

Grants Working Group Recommendations CLIN2 Clinical Trial Awards



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Review

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Our Mission

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



Strategic Impact Goals

Accelerating Discovery & Translation	Cell & Gene Therapy Approvals	Accessibility & Affordability of Therapies	Diverse Workforce Development
<p>Goal 1: Catalyze the identification and validation of at least four novel targets and biomarkers, ensuring integration into preclinical or clinical research for diseases in California</p> <p>Goal 2: Accelerate the development and utilization of 5-8 technologies that have the potential to improve safety, efficacy, and/or quality of cell and gene therapies</p>	<p>Goal 3: Advance 4-7 rare disease projects to Biologics License Application (BLA)</p> <p>Goal 4: Propel 15-20 therapies targeting diseases affecting Californians to late-stage trials</p>	<p>Goal 5: Ensure that every BLA-ready program has a strategy for access and affordability</p>	<p>Goal 6: Bolster CIRM's workforce development programs to address gaps and meet evolving demands in regenerative medicine</p>

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<p>Updated CLIN2</p> <ul style="list-style-type: none"> ➤ Allows for support of emerging novel clinical trial designs in CLIN2 program ➤ Incentivizes stage-appropriate market access strategy development and pre-commercialization activities in CLIN2 program ➤ Incorporates prioritization of innovative therapies for diseases that affect Californians 			

CLIN2 Program Objective

To support the completion of an interventional phase 1, 2, or 3 trial for an innovative stem cell-based or genetic therapy addressing a serious unmet need and with the potential for transformative benefits to patients, families and the health care system.

CLIN2 Program Structure

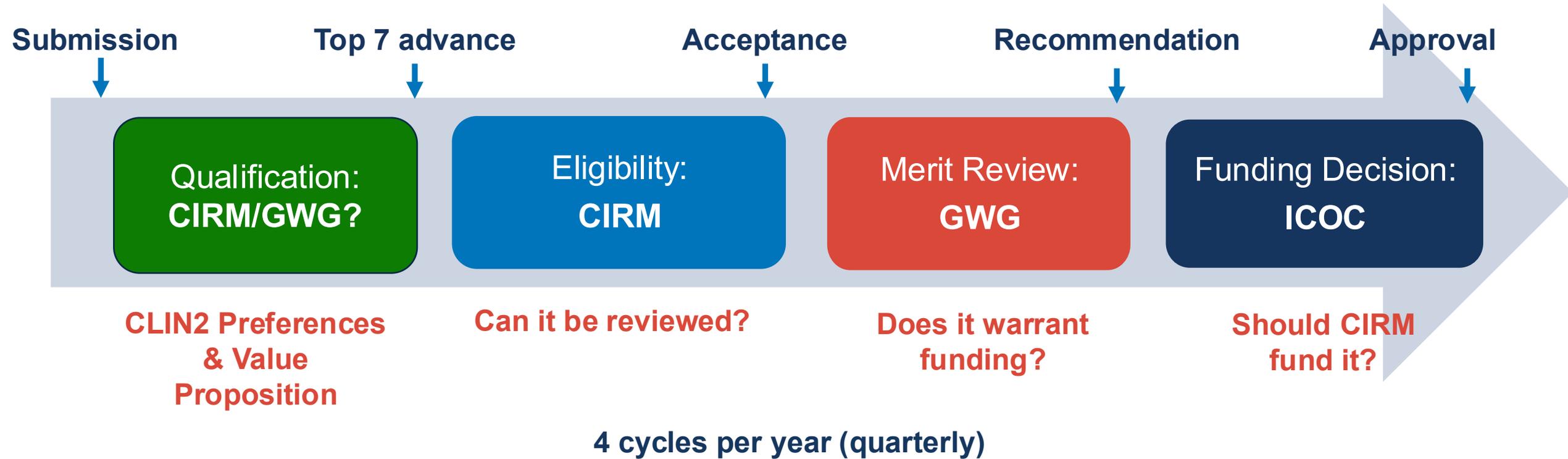
	CLIN2		
	First-in-Human	Phase 2 or subsequent*	Phase 3 or pivotal
Recurrence	4x per year		
Max Duration	4 years		
Applicant	California or non-California organizations		
Co-funding**	30% (for-profit) None (non-profit)	50% (for-profit) None (non-profit)	50%
Max Award (Total Cost)	\$8M (for-profit) \$12M (non-profit)	\$15M	\$15M
Awards/Year	9-16***		
Projection	9 x \$15M = \$135M		
Total Funds/Year	\$135M		

* Subsequent trials are Ph1 trials following a First-in-Human trial with the same candidate, disease indication and route of administration

** Co-funding is a percentage of total Allowable Project Costs

*** Number of awards is dependent on how many at each stage and organization status.

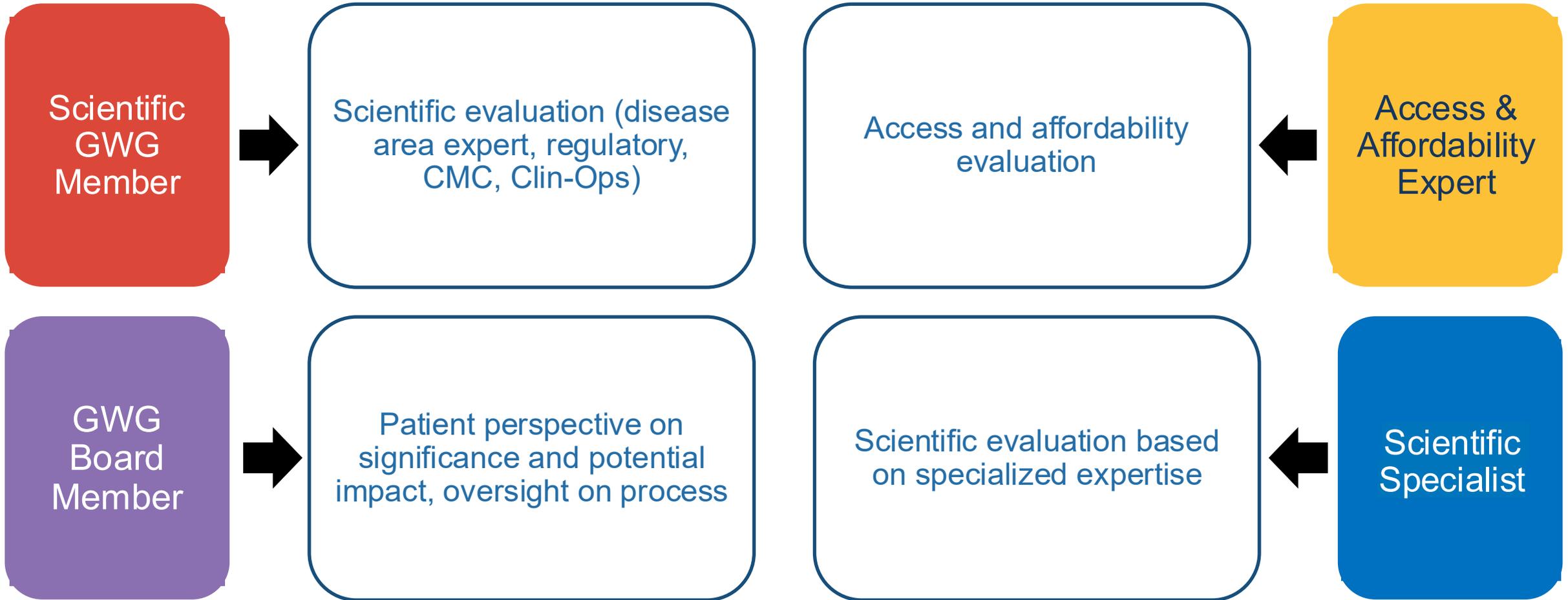
CLIN2 Application & Review Process



GWG – Grants Working Group

ICOC – Independent Citizens' Oversight Committee

CLIN2 GWG Panel Composition and Roles



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.

CLIN2 Scientific Review Criteria

1. **Value Proposition** - Evaluate the extent to which the therapy offers a compelling value proposition
2. **Rationale** - Evaluate the scientific rationale for the proposed therapy and the strength of the supporting data
3. **Project Plan and Design** - Evaluate the project's plan and design
4. **Project Team and Resources** - Evaluate the expertise and resources that will be deployed to achieve the project deliverables
5. **Population Impact** – Evaluate the extent to which the project considers the potential impact of the proposed therapy across affected populations

Access & Affordability

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

- Applicants complete an Access and Affordability (A&A) Proposal that is evaluated by a subject matter reviewer.
- A&A reviewers present their evaluations at GWG meetings along with the scientific and board reviewers.
- Access and affordability evaluations may inform scoring of the review criteria.
- For early-stage trials, deficiencies identified in A&A proposals may be addressed in the award period.

GWG Recommendations

Recommendation	Number of Apps	Total Applicant Request	Funds Available
Recommended for funding Score of 85-100	3	\$31,000,000	\$92,000,067
Not recommended for funding Score of 1-84	4		

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.

Minority Reports

- 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.

No CLIN2 applications qualified for a minority report this cycle.

CIRM Team Recommendations

App Num	Total Budget Request	GWG SCORE	Hi	Lo	Y	N	CIRM Recommendation
CLIN2-19270	\$15,000,000	85	90	84	13	1	FUND
CLIN2-19119	\$8,000,000	85	88	80	10	3	FUND
CLIN2-19416	\$8,000,000	85	89	70	9	5	FUND
	\$31,000,000						

CIRM Team concurs with GWG recommendations for funding