

Real

Life™

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Vice President Portfolio Development and Review

GWG Recommendations on Manufacturing Phase

One Awards

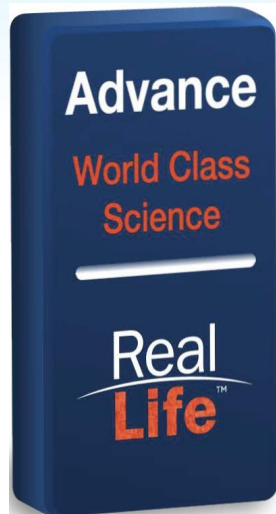
May 31, 2023

CIRM
CALIFORNIA'S STEM CELL AGENCY

OUR MISSION

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





- 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

Academic GMP Facilities



Industry Partners and National Organizations

- CDMOs
- Technology providers
- Investment and Partnerships
- NIIMBL
- NIST



Accelerate
and de-risk path to commercialization

Advance
standards and quality by design

Build
manufacturing leadership and workforce



- Manufacturing Network funding
- Alpha Clinics Network
- Education programs

Two phases of awards will be funded by two requests for applications

Phase One (this review)

- Fund academic GMP facilities to make initial progress to network goals



Phase Two (future RFA)

- Fund collaborative partnership-driven proposals that scale phase one efforts across the network

Steering Committee

Composed of awardees, industry partners and external representatives
Drive collaboration, knowledge-sharing and standard-setting

- Implementation of **quality-driven enhancements** that de-risk and accelerate early and late-stage process development and GMP manufacturing of cell and gene therapies.
- **Specialization** in one or more functional areas that overcome bottlenecks in the development and delivery of cell and gene therapies.
- **Workforce development** programs for technical and leadership positions, preferably in partnership with CIRM EDUC-funded programs, California cell and gene therapy industry stakeholders, and California academic institutions.

- **Knowledge Sharing:** Applicants should develop plans intended to capture and disseminate within the network any operational data, protocols, processes, expertise, guidance or other information vital to achieving the three goals of the California Cell and Gene Therapy Manufacturing network. The knowledge sharing plan may also include the ability to support CIRM TRAN and CLIN awardees that may utilize the Manufacturing Network in meeting their own CIRM data sharing requirements.
- **Organizational Business Plan:** Applicants are required to describe their plans for maintaining sustainability beyond the immediate project period of any proposed operational enhancements, quality-based improvements, specialization areas and training programs that will be developed, implemented and/or scaled up as part of these funding opportunities.

Must Include Plans to Address Underserved Communities

- How the proposed project activities will improve access to cell and gene therapies by underserved and disproportionately affected populations
- How the project team will bring diverse and inclusive perspectives and experience to the implementation of proposed activities
- How well the project team demonstrates a successful track record for promoting and valuing diversity, equity and inclusion (DEI)
- How any proposed workforce development programs will increase workforce participation by underserved and disproportionately affected populations in California

- The CIRM Board has allocated up to \$80M to support this program via two award phases.
- \$20M was allocated for Phase One awards (current opportunity).
- Phase One award provides up to \$2M for two years
- 9 applications were submitted and accepted for review
 - 3 applicants have relatively new manufacturing facilities
- GWG was instructed to recommend as many or as few as are meritorious

- **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 should provide recommendations that are achievable (i.e., “fixable changes”) or request clarification/information on key concerns.

- **Score of “3”**

Sufficiently flawed that it does not warrant funding.

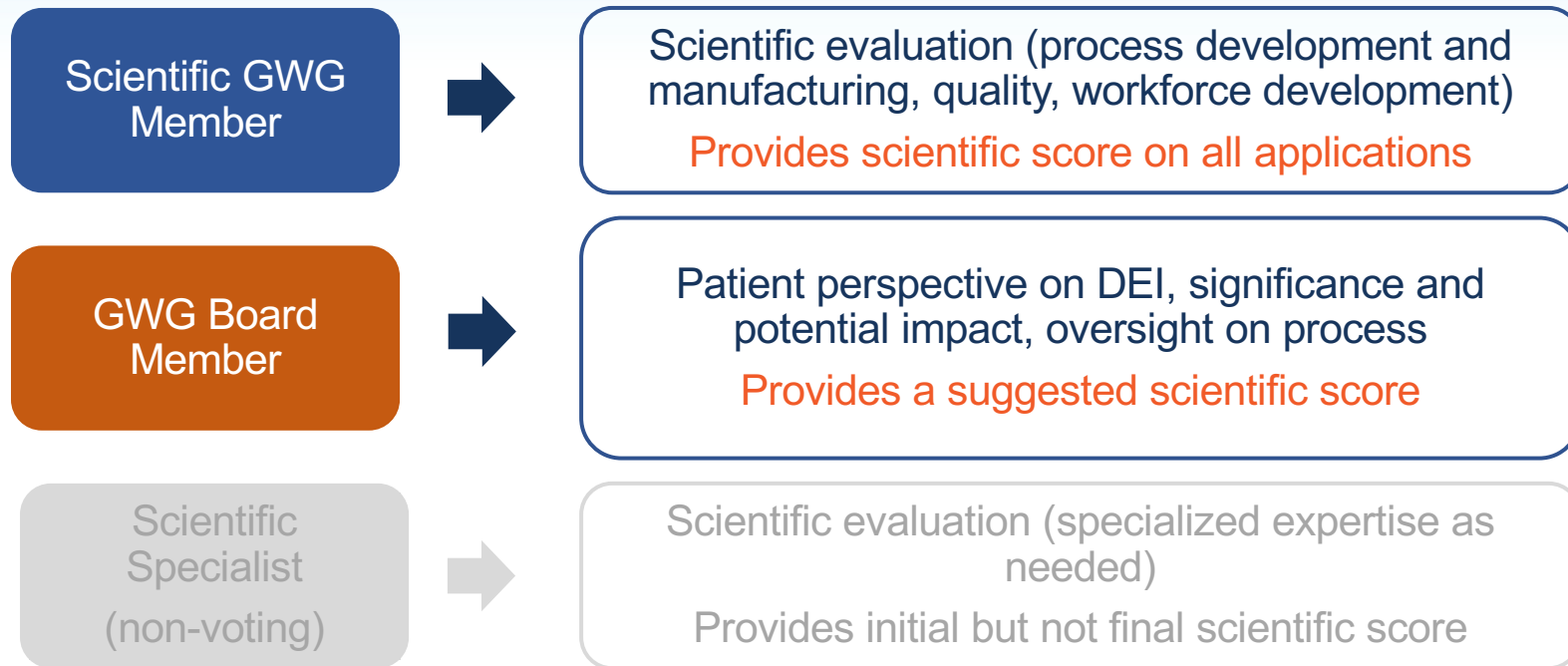
Applications are scored by all scientific members of the GWG with no conflict.

Scientific Review Criteria

Basis for Scientific Score

1. Does the project offer a significant value proposition that would contribute to the creation of a California Cell and Gene Therapy Network capable of accelerating manufacturing development, advancing industry standards in manufacturing and building an inclusive manufacturing workforce?
2. Is the project well planned and designed?
3. Is the proposal feasible?
4. Does the project effectively serve the needs of underserved and disproportionately affected communities?

- 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



GWG Recommendations

	Number of Apps	Total Applicant Request	Funds Available
Warrants funding Score of “1”	5	\$9,998,107	\$20,000,000
Needs improvement Score of “2”	4	\$7,496,937	
Does not warrant funding 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.



Applications with a Minority Report



App Number	Title	Funds Requested	Score	1	2	3
INFR5-14562	[Institution Name] Advanced Cell Therapy Laboratory	\$2,000,000	2	7	7	0
INFR5-14667	Advancing Cell Therapy Manufacturing Through Collaboration	\$1,999,964	2	5	7	0

App Number	Title	Funds Requested	Score	1	2	3
INFR5-14562	[Institution Name] Advanced Cell Therapy Laboratory	\$2,000,000	2	7	7	0
INFR5-14667	Advancing Cell Therapy Manufacturing Through Collaboration	\$1,999,964	2	5	7	0
INFR5-14779	Creating A Collaborative California Cell and Gene Therapy Manufacturing Network	\$1,496,973	2	0	10	5
INFR5-14574	The [Institution Name] GMP Cell and Gene Therapy Manufacturing Facility	\$2,000,000	2	0	9	5

The CIRM Team recommends that the 4 applications with a score of “2” be given the opportunity to revise and resubmit their application and allow the GWG to evaluate the revisions.

The CIRM Team agrees with the GWG recommendations to fund applications with a score of “1”.

Board members with Conflicts of Interest for INFR5 applications

Haifaa Abdulhaq	James Kovach
Kim Barrett	Pat Levitt
Maria Bonneville	Linda Malkas
Linda Boxer	Shlomo Melmed
Ysabel Duron	Christine Miaskowski
Leon Fine	Suzanne Sandmeyer
Elena Flowers	Michael Stamos
Judith Gasson	Keith Yamamoto
Larry Goldstein	