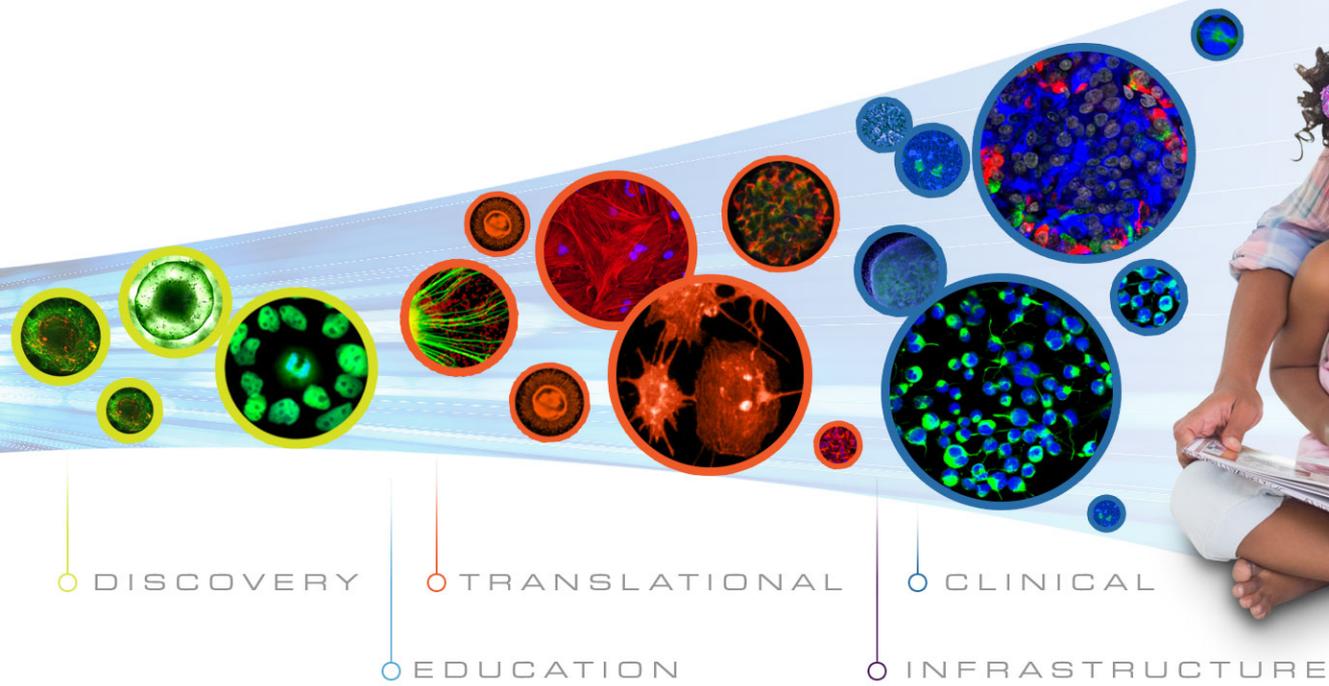


CIRM

CALIFORNIA'S STEM CELL AGENCY



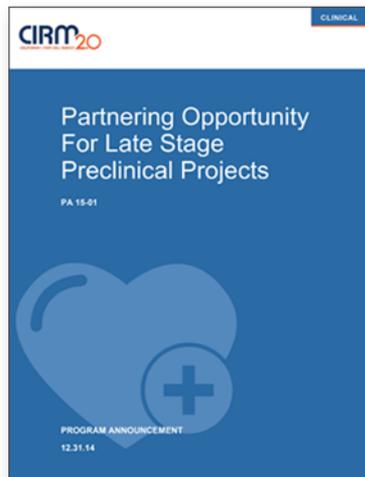
GWG Review of Clinical Program Applications

Gil Sambrano

Director of Portfolio Development and Review

Clinical Stage Programs

CLINICAL STAGE



CLIN 1



CLIN 2



CLIN 3

Scoring System for 2.0 Applications

- **Score of “1”**

Exceptional merit and warrants funding.

- **Score of “2”**

Needs improvement and does not warrant funding at this time but could be resubmitted to address areas for improvement.

- **Score of “3”**

*Sufficiently flawed that it does not warrant funding and the same project should not be resubmitted **for at least 6 months.***

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

CLIN1-08686: Preclinical Development of a Cell Therapy for Corneal Blindness

Therapy: Cultivated patient-specific corneal epithelial stem cells (limbal stem cells, LSC)

Indication: Corneal blindness as a result of injury and inability to heal due to corneal epithelial stem cell deficiency

Goal: Complete preclinical research activities needed to submit an IND and support a future clinical trial.

Major Proposed Activities:

- LSC manufacturing development and certification
- Establish manufacturing process in a GMP facility
- Biomarker development

Funds Requested: \$4,244,211 (\$0 Co-funding)

CLIN1-08686: Preclinical Development of a Cell Therapy for Corneal Blindness

Budget Review: Pass

GWG Score: 1* Exceptional merit, warrants funding

- Votes for score of 1: **9**
- Votes for score of 2: **1**
- Votes for score of 3: **0**

CIRM Team Recommendation: Fund (concur with GWG recommendation)

Award Amount: \$4,244,211

*Revised application score – originally scored 2 (1-11-0) and (4-7-0)

CLIN1-09187: Preclinical Development of a Cell Therapy for Chronic Wounds in Diabetics

Therapy: Autologous stromal vascular fraction cells isolated at point of care

Indication: Ulcers and chronic wounds associated with diabetes

Goal: Complete preclinical research activities needed to submit an IND and support a future clinical trial.

Major Proposed Activities:

- Prepare IND and Investigator's Brochure
- Conduct additional product characterization study
- Institute endotoxin testing into clinical workflow

Funds Requested: \$75,800 (\$0 Co-funding)

CLIN1-09187: Preclinical Development of a Cell Therapy for Chronic Wounds in Diabetics

Budget Review: Pass

GWG Score: 3 Does not warrant funding and should not be resubmitted for at least 6 months

- Votes for score of 1: **0**
- Votes for score of 2: **2**
- Votes for score of 3: **9**

CIRM Team Recommendation: Do not fund