

**SOMETHING
BETTER
THAN HOPE**

**Amendments to DISC, TRAN and CLIN
Concept Proposals**

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Background

- CIRM has historically offered recurring discovery (DISC), translational (TRAN) and clinical (CLIN) funding opportunities to support stem cell-based research. In the last two years, limits on available budget have prevented opening some of our core programs and/or modifying them to address urgent needs such as COVID-19.
- CIRM is proposing changes to the DISC, TRAN and CLIN concepts to effectively relaunch these core programs starting January 2021 under Proposition 14.

Background

- The proposed initial relaunch of the core programs would restore features such as award limits, award duration and other elements to that available before the COVID-19 program was implemented.
- The proposed concepts would retain and enhance recent elements such as addressing the needs of underserved communities and add new requirements such as a requirement for a data sharing plan.
- The changes also align the concepts with Prop 14 requirements and definitions.

Global Changes to DISC, TRAN and CLIN Concepts

- Addition of requirement for applicants to provide a Data Sharing Plan and allowance to include related costs in budget.
- Removal of requirement to deem gene therapy projects a “vital research opportunity” by the GWG.
- Broadly included gene therapy projects as in-scope for CIRM funding.
- Add a review criterion for GWG and ICOC (Application Review Subcommittee) evaluation of applicant statements and plans to address the needs of underserved communities.

General Process for DEI in Application Review

- CIRM proposes to consider diversity, equity and inclusion (DEI) in the assessment of applications.
- Review criterion for GWG and ICOC (Application Review Subcommittee) to evaluate scientific elements such as enrollment and outreach plans in clinical trials and incorporation of diversity in research design will be used as part of score and critique.
- In addition, how the applicant incorporates DEI more broadly to support the project will be considered by patient advocate members of the GWG and recommendations forwarded to the Application Review Subcommittee for programmatic review.

Proposed Changes to DISC2 Program

Discovery awards to identify a candidate therapeutic, medical device, diagnostic, or tool

- Award limit restored to direct project costs of up to \$900,000 for therapeutic candidates and \$500,000 for a diagnostic, device or tool.
- Maximum award duration restored to 24 months
- PI percent effort requirement restored to 20%
- Project initiation updated to within 60 days of approval

Proposed Changes to TRAN Program

(TRAN1, TRAN2, TRAN3, TRAN4)

Translational awards to advance a candidate therapeutic, medical device, diagnostic, or tool to the clinic or commercialization.

- Project initiation updated to within 60 days of approval

Proposed Changes to CLIN Program (CLIN1, CLIN2, CLIN3)

Awards to support IND-enabling activities and clinical trials

- Award limit restored for clinical trials in CLIN2
- Award duration restored to a maximum of 4 years for CLIN2
- Project initiation restored to within 45 days of approval for CLIN2
- Changed percent effort requirement for project manager to 50% for CLIN2
- Clarified that minimally manipulated bone marrow, cord blood or unmodified HSC are eligible candidates for phase 2 or phase 3 clinical trials

Requested Action

CIRM requests the Board approve the proposed amendments to the DISC, TRAN, and CLIN concept plans.