



TO: Chairman Thomas and Members of the ICOC
FROM: C. Scott Tocher, General Counsel
DATE: March 13, 2018
RE: Amendments to DISC and CLIN Concept Plans

Background

The Board approved concept plans for CIRM's Discovery ("DISC") and Clinical ("CLIN") programs in 2015 and has continued to refine the concept plans to address programmatic and operational needs. For the reasons discussed below, the CIRM team recommends amending the DISC2 Quest program to eliminate the follow-on Incentive Award component, and to limit the project period for CLIN awards to 48 months.

Proposed Amendments

1. DISC2 Quest Awards – Eliminate Incentive Grant Opportunity

To accomplish CIRM's goal of accelerating and advancing the discovery of novel stem cell treatments, the agency established three types of Discovery Stage Programs: 1) DISC 1 – Inception Awards; 2) DISC 2 – Quest Awards; and 3) DISC 3 – Challenge Awards.

The objective of the DISC-2 funding opportunity is candidate discovery, specifically to promote the discovery of promising new stem cell-based technologies that could be translated to enable broad use and ultimately improve patient care. Projects funded through the Quest Awards should propose technology that is uniquely enabled by human stem/progenitor cells or directly reprogrammed cells, or uniquely enabling for the advancement of stem cell-based therapies. Currently, a successful Quest applicant is eligible for direct project costs of up to \$500,000 to achieve a candidate that is a diagnostic, device or a tool; \$900,000 is available if the candidate is a therapeutic. The project period for a Quest Award is up to two years, and an additional 6-month no-cost-extension is available.

As part of the original construct of the DISC2 program, an additional component called an "Incentive Grant" is available to Quest Award recipients who, within a year of the close of their Quest Award, achieves a "progression event." Under this component, \$150,000 in direct project costs is available to Quest Award recipients who acquire funding for subsequent development of the Quest Award deliverable, or "passes the

baton” to another qualified team for further development. This component can fund a DISC1 – Inception Award project proposed by the Principal Investigator and subject to CIRM’s prior approval. The project period for this component can be as long as two additional years (in addition to the term of the underlying Quest award).

Factoring in the project period for the Incentive Grant component, as well as the no-cost-extension allowance, the Incentive Grant component is incompatible with CIRM’s current projected lifespan. In addition, elimination of this component will free up research funding for other programmatic priorities.

2. CLIN Awards – Limit Project Period to 48 Months

Currently, the concept plan for CLIN awards does not describe a limit to the project period for successful applicants. As a practical matter, however, applicants are required to propose a project and timeline that demonstrates an urgency that is commensurate with CIRM’s mission. For instance, part of the review criteria used by members of the Grants Working Group when evaluating a proposal is whether the proposed experiments are essential and whether they create value that advances CIRM’s mission. Reviewers also evaluate the proposal to determine if the timeline appropriate to complete the essential work without unnecessarily extending it for non-essential activities. Nevertheless, and because some proposals propose activities extending five years and beyond, the concept plan should be amended to clearly state the appropriate project period limit.

Consistent with CIRM’s current projected lifespan, the team proposes limiting the project period of an award to 48 months. This will ensure that the last CLIN awards forecast to be awarded in 2019 do not extend beyond the agency’s budgeted management of awards.

Requested Action: CIRM requests the Board approve the proposed amendments to the DISC and CLIN concept plans.

Attachments