



TO: Members of the ICOC

FROM: Patricia Olson, Ph.D. Executive Director, Discovery

DATE: September 10, 2015

RE: Proposed Updates to the Discovery and Translation Program (D&T) Concept Plans and Clinical Concept Plan

Background

On July 23, 2015, the ICOC approved concept plans for the Discovery (PA 15-07, 15-08 and 15-09) and Translation Programs (PA 15-10, 15-11, 15-12 and 15-13). Last year, the ICOC approved the concept plan for CIRM's Clinical Program. After further consideration of the concept plans, the CIRM team would like to make two modifications, described below. The Science Subcommittee met on September 8, 2015, to consider the proposed amendments to the Discovery and Translation concept plans. After considering the CIRM team's presentation, the Subcommittee unanimously recommended ICOC approval of the modifications.¹

Proposed Changes:

1. Change the loan election option. Under the Translation Program concept plan approved by the Board in July, an applicant who received an award for early development for a therapeutic (PA 15-10), a diagnostic (PA 15-11), or a device (PA 15-12) could elect to treat the award as a loan within the earlier of a specified period or a regulatory submission for marketing. The same is true for a Clinical Program awardee who seeks to develop a therapeutic or device. Since the Board approved the concept plans, the CIRM team has continued to refine the loan election policy in order to establish an appropriate rate of return. In order to avoid the complexity associated with establishing repayment terms for diagnostics and devices, which have variable regulatory pathways, we propose to offer the loan option only to therapeutic development awardees under terms to be specified in the Clinical and Discovery and Translation Program Grants Administration Policies, which will be presented to the Board for consideration later this Fall. Of course, the CIRM team will continue to monitor this program and if the absence of a loan option proves to be a barrier to entry for awardees seeking to develop diagnostics or devices, we will return to the Board with a request to modify the program.

¹ The Science Subcommittee did not consider the request to amend the Clinical Program concept plan, but the proposal, discussed in paragraph (1), would merely conform the treatment of loans under the Clinical Program concept plan with the treatment of loans under the Translation Program concept plan.



2. Eliminate Specificity in the Discovery and Translation Concept Plans Regarding Application Schedule and Deadlines. The Translation and Discovery Program concept plans approved by the Board in July included details (“Schedule and Deadlines”) regarding the timing and order of the submission of applications for various programs announcements that fall under the Translation and Discovery Programs. In order for CIRM to operate efficiently and to respond to changing circumstances and needs, CIRM must be nimble and flexible. To ensure that the CIRM team has the ability to make adjustments to the program schedule to meet these needs, we propose to eliminate the specificity in the Translation and Discovery Program concept plans regarding the schedule for the submission of applications in response to program announcements issued under these programs.

Recommendation: Approve proposed amendments to the Translation and Discovery Program and Clinical Program concept plans to: (1) offer an option only to therapeutic development awardees under the Clinical and Translation Programs to treat their award as a loan under terms to be presented to the Board as part of the Clinical and Discovery and Translation Program Grant Administration Policies; and (2) eliminate the specificity detailed in the Discovery and Translation concept plans regarding the schedule for submission of applications in response to program announcements issued under these programs.