

Proposal for an Opportunity Fund Program

Objectives:

- Accelerate development of stem cell therapies, (as set forth in Proposition 71)
- Implement recommendation of the External Review Panel to “Pave a path from fundamental to translational research, translational medicine, product development and healthcare delivery” by a “Transition to a much more proactive strategy of funding that aligns CIRM’s peer review and other processes with its mandate of delivering new treatments to the clinic as articulated in CIRM’s mission and strategic goals”.
- Implement the recommendation of the External Review Panel to adopt a “porous opportunity model rather than an internal pipeline model...[to] keep California as the hub of clinical proof of concept in regenerative medicine for the world rather than just for CIRM funded pipeline projects.” (Recommendation 5)
- Attract industry participation through a funding mechanism that is more aligned with industry’s financing practices as recommended by the External Review Panel. (Recommendation 7)

Description of Potential Opportunity Fund Programs

To meet the above objectives, we propose that the Governing Board (ICOC) authorize creation of an opportunity fund. Initially, we propose a Bridge Funding Program, described below, that would access such an opportunity fund; we are developing two additional programs that would benefit from access to an opportunity fund as well. These include a California/External Innovation Funding Program and an 3) Industry Strategic Partnership Program. Each of these are briefly described below.

- **“Bridge Funding Program”** provides supplemental funding for selected existing CIRM funded projects to enable uninterrupted funding of development activities (but not new patient enrollment) to occur until the next relevant RFA/review is offered. Projects that are proposed for opportunity funding under this program must be mission critical, competitive and in ‘good standing’ (meeting milestones, on track for planned outcome). Those projects that receive bridge funding would be required to submit an application to the next applicable RFA/GWG review but would not be required to participate in a pre-application/planning award process.
 - Only active CIRM funded projects, previously reviewed by the Grants Working Group and approved by the ICOC, would be eligible for Bridge Funding. Specifically, only the following translational and development projects would be eligible for funding from a Bridge Opportunity Fund:
 - Early Translational projects targeting a Development Candidate
 - Disease Team projects
 - Targeted Clinical Development Projects
 - Propose an initial \$25M opportunity fund for Bridge Funding Program, subject to replenishment by the ICOC

- CIRM to report to the ICOC on Bridge Funding disbursements when requesting replenishment or at least annually
- Implementation
 - Maximum opportunity fund supplemental funding is \$5 MM. President has authority to approve (Note: a DT award amortized equally over 4 years would be \$5 MM/yr. A year is expected to be the maximum bridge period)
 - Internal staff recommendation is required to initiate process for supplemental Bridge funding. Recommendation based on significance to mission, competitiveness, project performance, timing (relative to next RFA), and other defined criteria.
 - Following internal recommendation, and receipt from the grantee of, minimally, a description of the proposed work, a detailed budget and justification, the project will be considered by the next Clinical Development Advisory Panel (CDAP) meeting for review against set criteria (for example, see DT RFAs). Based on CDAP advice, the VP, R&D and staff will advise the President who will make supplemental funding decision. (To reduce the burden on the CDAP, for those recommended projects that want to “bridge” from Early Translational Development Candidate into IND-enabling preclinical development, consider using an internal staff review, in association with external expert consultants.)
 - As noted above, projects that receive Bridge funding would be required to submit an application to the next applicable RFA/GWG review (but would not be required to undergo pre-application/planning award review)

- “CA/External Innovation Funding Program” enables the ICOC to authorize timely short-term one year funding to new projects where an external high impact research opportunity has been identified through an inventory of the research landscape, collaboratively partnered with a California researcher and the team is assembled and research is available for immediate implementation.
 - Projects that are proposed for opportunity funding of the California component under this program could be:
 - Early and applied research on cutting edge technologies
 - Preclinical/clinical development stage programs that could provide the needed preliminary data to support the submission of a more comprehensive program in an emerging field critical to advancing stem cell science.

- “Industry Strategic Partnership Program” enables the ICOC to commit to funding for preclinical, first in man studies and Phase II studies for projects satisfying the accelerated review eligibility requirements and receiving GWG recommendation.
 - Projects that would be eligible for funding from an opportunity fund include those that
 - Are in preclinical development, are in ‘good standing’ (meeting milestones, on track for outcome of IND filing) and are funded by CIRM through IND filing
 - Are investment ready as evidenced by venture, or industry partnership commitments

