WEBINAR – 7 August 2013
RFA 13-03: CIRM Strategic Partnership III Awards

Questions and Answers

Questions	Answers
1. If a company qualifies for Track A, can it submit an application under that Track by itself and also submit for Track B with a pharma partner?	The applicant must choose either Track A or Track B but cannot do both.
2. Is the major development milestone the outcome that is evaluated at the completion of the trial? Can funding be provided on an incremental basis throughout the project, or only at the end?	Under Track B there will be only one payment, triggered by successful achievement of the Major Development Milestone.
3. For the subcontractor limit of $25,000 can we spend the collaborator's contribution over the limit outside of California?	Yes. There are no restrictions on where matching funds can be spent. Please note that the limit of $25,000 applies only to CIRM funding and only to contracts for *research* to be performed outside of California. For activities other than research, Grantees may use CIRM funds to subcontract outside California. Please see the RFA for definitions of 'research' and 'not research'.
4. What are the requirements for the PI and how will that be assessed?	The PI must have an M.D., Ph.D. or equivalent degree to be eligible. Relevant experience in leading and guiding a development project into the clinic is a review criterion. Please see the RFA and review criteria for further details.
5. LOI – For the term sheet for collaborators (Aug 22nd deadline), is it acceptable to have the terms under negotiation?	Yes. For the LOI, the minimal requirement is a letter from the biotechnology or pharmaceutical company indicating that it is interested in co-funding the proposed project and that the parties are negotiating the terms of support.
6. Besides the forms on the website, what is needed for the Aug 22nd deadline?	Any documents needed to establish commercial validation. Please see Section VIII.A of the RFA.

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7. Would another company or organization using our cells for a different application and indication negatively affect our application? Is there an informal limit?	This would be evaluated by the Reviewers and is likely to depend on the specifics of the applications.
8. What is the evaluation process for the LOI?	Applications at the LOI stage are internally evaluated by science and review staff solely for eligibility, based on the requirements set forth in the RFA. An application must meet the required eligibility criteria in order to proceed to the application stage for review.
9. How much information should be included in the conflicting IP section?	There should be sufficient information to make reviewers aware if there is a potential risk for the program, and if so, that the applicant is aware of the risks and has a mitigation plan.
10. Should in-kind contributions be included in the budget?	Yes. If this is an important part of the applicant co-funding, the in-kind contributions should be detailed in the activities-based budget (Part E of the application) as well as in Part A.
11. For Letters of Support from leading clinicians, where should that be included in the application? Supplemental Information? Will they be considered?	Letters of Support should be submitted as part of the full application (in Part C) and will be considered in the review.
12. What are the guidelines for clinical sites? Do all the sites need to be in California? One site in California? 50%?	For any clinical trial that is part of the proposed project, at least one of the clinical sites implementing the protocol must be in California.

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13. If a non-profit applies, is it required that they have had $10 million in contributions the past 2 years or does that only apply to for-profits?	No, it is not required for non-profits. This applies only to **for-profit** applicants seeking to establish Commercial Validation via Financial Strength. **Non-profits must have a collaborative research agreement** with a large biotechnology or pharmaceutical company having a market capitalization of at least $500M, to be eligible.
14. Are medical device companies allowed to be collaborators ($500 million market cap) or only Bio/Pharma?	Yes, if they are willing to provide the required co-funding for the project.
15. Are there limits to the supplemental information that will be considered?	Yes. Please see Section VIII.D or contact CIRM.
16. If a company obtained an award under Track A in this call, would it then be subsequently eligible for future Track B calls?	There is no automatic eligibility. If Track B were offered in a future round of the Strategic Partnership Initiative, it would depend on the stated eligibility criteria for that call of the RFA.
17. Must a PI be 1) a full-time employee or 2) employed by the time of application (21 Oct)?	It is CIRM's expectation that the PI will be employed at least 50 percent time by the applicant organization at the time of the application. The RFA requires the PI to commit a minimum of 30 percent (of full time) effort to the project. That 30 percent effort, and all additional PI effort paid for with CIRM funds, must be performed in California. However, the PI need not be working in California prior to the time of award.

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18. RFA requests GAAP financials as of June 30, 2013 but we have closed a round of funding since then. Are supplemental financials from a different point of time ok?	Yes, please include any updated and/or pro forma financials since the most recent quarter.
19. Specifically, how will a Track B application be reviewed differently than a Track A application?	The emphasis in review criterion C, 'Design and Feasibility', is different for the 2 tracks. Please see the RFAs for specifics.
20. What if the PI has agreed to employment at the company at a future date, e.g., Q1 2014?	The PI must be an employee by the application due date (see Question #17).
21. The commercial validation section on the portal makes reference to a template. Where can that template be found?	Go to the 'upload documents' page of the web based LOI form. You will be able to download the template by selecting it.
22. When should we expect to hear from CIRM if we are invited to submit a full application?	Applicants will only be notified if the LOI was NOT accepted.
23. If an LOI will be reviewed for eligibility of the submitting company for either Track, when will CIRM inform the submitter?	Applicants can submit to either Track A or Track B, but not both. It is the applicant's decision as to which track would be more suitable. Please contact CIRM is you need assistance in making this decision.

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24. Track B - Is CIRM the ultimate decider of whether the Major Development Milestone has been met?	The Major Development Milestone and success criteria will be agreed to between CIRM and the applicant at the start of the project. The final data will be assessed by CIRM's external Clinical Development Advisory Panel, who will provide advice to CIRM, and CIRM will make the final decision as to whether the Major Development Milestone has been achieved.
25. Track B - Phase 1 studies are typically designed to evaluate safety and gather initial dosing information, not to evaluate efficacy in a statistically significant manner. For a Phase 1 study under Track B, what would determine success?	Success criteria would be determined on a case-by-case basis. Although Phase 1 trials are not specifically designed to evaluate efficacy, they could meet the objective of the award (to provide some evidence that the therapy is having a promising clinical effect) using a clinically meaningful biomarker that is relevant for the target indication.
26. Track B - From the perspective of an applicant, there are other development milestones that are meaningful, such as completing a Phase 1 trial to establish safety and dosing parameters for a subsequent Phase 2 study. Would establishing safety and dose alone be sufficient as the Major Development Milestone in Track B?	No. CIRM is asking to see some evidence that the candidate therapy has clinically meaningful activity in humans.
27. Track B - If a company already has the resources to complete Phase 1 and/or Phase 2 studies, why would they apply?	For those projects that are successful, the Milestone payment would provide up to $10M per project for up to 5 projects, to help move the project forward to the next stage in development.