WEBINAR – May 14, 2014
RFA 14-03: CIRM Strategic Partnership IV Awards
Questions and Answers

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1. What is the definition of the principal Investigator (PI) for this RFA? Does PI have to be the Clinical Lead of the project?	The PI is a designated point of contact for CIRM and is a person responsible and accountable to CIRM for scientific performance on the project. The PI must: (a) be an employee of the applicant organization; (b) commit to a minimum of 30% time working on the project in California; (c) have demonstrated expertise in drug development; and (d) have demonstrated expertise in managing clinical research programs. The PI does **not** have to be a clinical lead on the project.
2. Can you elaborate on the necessary evidence of commercial validation? How is financial strength defined?	If the applicant is a **for-profit** - A) it must have raised a minimum of **$10 Million** in the last 2 years through public or by VC firms or biotech/ pharma , foundations or govt. entities. B) it must have at least one year of operating expenses on its balance sheet in cash or cash equivalent (based on last 12 months of operating expenses). If the applicant is a **Not-for profit –** it must have a collaborative research agreement with a large biotech/pharma partner with a market cap of at least $500 million and that partner must agree to provide the financial /in kind support for 1:1 match

3. Are clinical sites outside of California allowed?	CIRM requires that clinical trials proposed for funding must include clinical trial sites in California. If the total number of proposed clinical sites is less than 20, then at least one site must be in California. For trials with 20 or more sites, at least 10% of the sites must be in California. Clinical trial sites outside of California are allowed as long as they meet the requirements for clinical sites in California.
4. Is an investigator –sponsored IND allowed?	Yes. For investigator-sponsored INDs, the investigator-sponsor must be the PI on the CIRM grant. For an organization-sponsored IND, the organization sponsor must be the applicant organization on CIRM application and PI must be an employee of the applicant organization.
5. Is this RFA open to a for-profit organization that holds a CIRM Disease Team or Strategic Partnership award?	For-profit applicant organizations that hold **2 or more** of the CIRM Disease Team, Disease Team Therapy Development or Strategic Partnership Awards as of application due date (September 9, 2014) are not eligible to apply for this RFA.
6. In the past there has been only one awardee per cycle. How many awardees are possible if you assume $10M each?	The CIRM board has allocated $32 million for up to 3 projects

7. Are there any preferred or higher priority therapeutic areas?	CIRM's priority is to support the development of stem cell based therapies for unmet medical needs in all therapeutic areas in regenerative medicine.