



**November 27, 2011**

**From:** Ellen G. Feigal, M.D., Senior Vice President, Research and Development

**To:** ICOC/Board

**Re:** Pre-read for Strategic Plan Update Meetings at ICOC/Board on December 8, 2011

The attached document serves as a pre-read for the upcoming Independent Citizens Oversight Committee (ICOC) Board Meeting in Los Angeles, CA, on December 8, 2011. Our objectives for the ICOC/Board topic are to provide you an update on our recent meetings; summarize stakeholder sessions being planned, and identify what types of additional information you would find useful to inform a more detailed discussion of the Strategic Plan at the ICOC/Board meeting in January, as we prepare for the final consideration of the Strategic Plan at the March ICOC/Board meeting.

We have provided a summary of the key discussion points from our 5 recent meetings: 2 public meetings, one in Los Angeles and the second in San Francisco, and 2 industry meetings, one in San Diego and the second in South San Francisco, in addition to our meeting with the ICOC/Board on October 26<sup>th</sup> at UC Irvine. At the ICOC/Board meeting in December, we plan to provide a concise recap of the information provided in this document, identify where we are in the timetable of revising the strategic plan, convey inputs from stakeholders received to date, including those from our Collaborative Funding Partners, the Alliance for Regenerative Medicine, an Industry Advisors Council, and summarize stakeholder discussions being planned, including those with Patient Advocate organizations, Clinical Development Advisors, the International Society of Stem Cell Research, and the International Society of Cell Therapy.

Thanks very much, and we look forward to an interactive and productive discussion.



## Project Overview

### Current Situation

**The Strategic Plan of the California Institute for Regenerative Medicine (CIRM) is a living document that requires regular updates incorporating feedback from various sources.**

- CIRM maintains a Strategic Plan, ***initially written in 2006 and updated in 2009/2010***, in preparation for review by an External Review Panel (ERP).
- An ***ERP review in October 2010*** generated key recommendations for this update.
- CIRM needs to ***update the Strategic Plan to reflect the ERP recommendations*** and other shifts in the field, and the process of updating the Strategic Plan will continue through ICOC approval in March of 2012.
- Discussions to date include the following:
  - CIRM senior staff retreat on August 18, 2011; Science Team discussion on August 23, 2011
  - Process update to ICOC on August 25, 2011
  - Stem Cell Research Leaders discussion on September 13, 2011
  - Meetings with the Public on October 25, 2011 and October 31, 2011
  - Meetings with Industry on October 27, 2011 and October 28, 2011, and meeting with Industry Advisors November 10, 2011
  - Meetings with the ICOC on October 26, 2011
  - Telecons with Collaborative Funding Partners on November 15 and November 18, 2011; Telecons with leaders of the Alliance for Regenerative Medicine November 21, 2011.
- Planned discussions include the following:
  - Telecons with Clinical Development Advisors November 28, December 2, and December 5, 2011; Telecon with leaders of the Int'l Society for Cellular Therapy November 28, 2011; Telecon(s) with Patient Advocate Organizations early December, 2011
- The Strategic Plan will be ***shared with the IOM Review Committee***.

*As in prior years, CIRM seeks ICOC(Board) perspectives, and is seeking stakeholder input from patients, patient advocacy organizations, members of industry, other members of the public, to embed in the revised 2012 Strategic Plan.*

## **Project Overview**

### **Approach**

1. Define the Strategic Plan (Internal)
2. Seek ICOC (Board) and Stakeholder Input (External)

Meetings with: Public, Industry and ICOC/Board meetings

Dialog with Professional organizations (Int'l Society Stem Cell Research, Int'l Society for Cellular Therapy, Alliance for Regenerative Medicine), Collaborative Funding Partners, Clinical Development Advisors, and Patient Advocate Organizations

3. Embed Input and Finalize Strategic Plan

**This document focuses on step two and provides the common themes for consideration provided by ICOC (Board) and the external stakeholders.**

## **Project Overview**

### **Stakeholder Input Objectives**

**CIRM's objectives of seeking stakeholder input on the 2012 Strategic Plan update were three-fold:**

1. Obtain perspectives on how well CIRM is doing in achieving its goals
2. Determine whether the proposed revisions to CIRM's strategic objectives and strategies are appropriate
3. Identify additional areas and/or activities for CIRM to consider or focus on moving forward

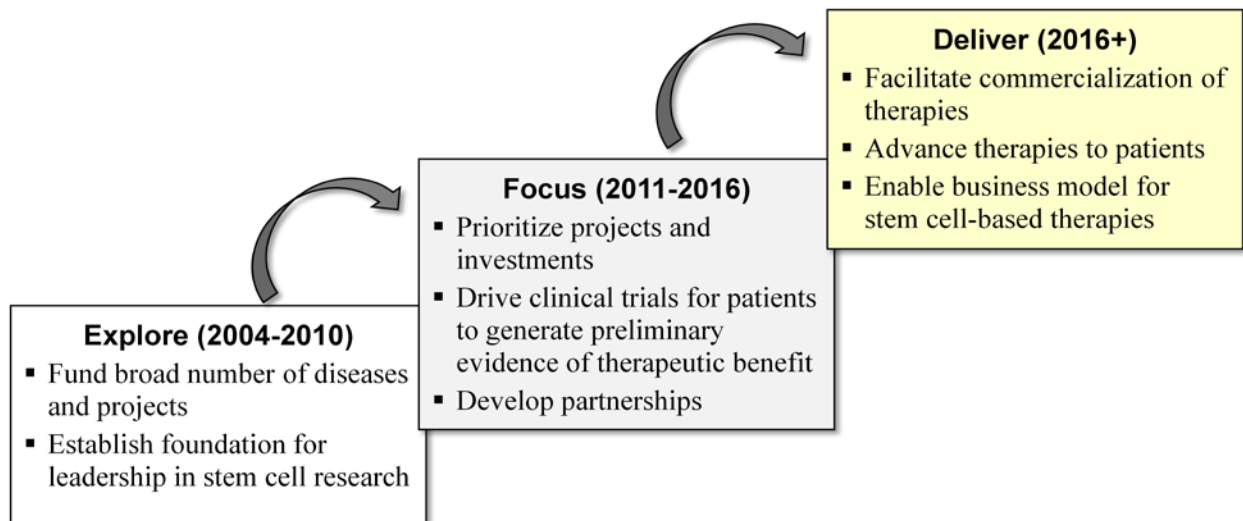
*To address the above objectives, five meetings across California with a variety of public, industry, and ICOC stakeholders.*

## Draft 2012 Strategic Plan Elements

### CIRM Mission and Vision

CIRM's overarching mission and vision for execution remain constant between the 2009/2010 and the 2012 versions of the Strategic Plan.

“To support and advance stem cell research and regenerative medicine under the highest ethical and medical standards for the discovery and development of cures, therapies, diagnostics, and research technologies to relieve human suffering from chronic disease and injury “



## Draft 2012 Strategic Plan Elements

### Proposed Changes to 2009/2010 Strategic Objectives

In 2009/2010, CIRM outlined five strategic objectives. The proposed approach for 2012 is to streamline these into four key strategic objectives that better align to the overarching mission and vision.

2009/2010 strategic objectives					
	Acceleration of Therapeutic Discoveries	Operational Excellence	Regulatory Certainty	Public Education	Economic Benefit to California
<i>Rationale for Change</i>	Morphed into science and medical benefit	Underpins all objectives	Became a strategy	Morphed into social benefit	Remains




Proposed 2012 strategic objectives			
Scientific Objective	Medical Objective	Economic Objective	Social Objective
<b>Accelerate understanding of stem cell science</b> and its applications towards human diseases and injuries	<b>Advance science into clinical trials</b> to achieve preliminary evidence of therapeutic benefit to patients	<b>Drive economic development</b> for California from stem cell science	<b>Increase awareness</b> of California as the leader in stem cell research and therapies

### Draft 2012 Strategic Plan Elements

Proposed 2012 Strategies underlying each proposed Strategic Objective

Scientific Strategies	Medical Strategies	Economic Strategies	Social Strategies
<ul style="list-style-type: none"> <li>▪ Enhance footprint (intellectual, IP, and physical infrastructure)</li> <li>▪ Build partnerships with industry</li> <li>▪ Increase scientific research collaborations</li> <li>▪ Leverage expertise</li> <li>▪ Revise prioritization and decision-making framework</li> </ul>	<ul style="list-style-type: none"> <li>▪ Prioritize/be more selective at all stages of the process</li> <li>▪ Ensure that there is a pathway forward (regulatory, commercial)</li> <li>▪ Build partnerships with industry, medical community, and global organizations</li> <li>▪ Engage patients and advocates early</li> </ul>	<ul style="list-style-type: none"> <li>▪ Leverage investment through partnership</li> <li>▪ Partner with California government</li> <li>▪ Empower California Economic Development agency</li> <li>▪ Draw companies to California</li> </ul>	<ul style="list-style-type: none"> <li>▪ Communicate value proposition</li> <li>▪ Broaden communication, education, and messaging</li> <li>▪ Partner with patient advocacy groups and the state of California</li> <li>▪ Increase global outreach efforts</li> </ul>

## ICOC (Board) Discussion and Stakeholder Input Meeting Overview

-  Public Meeting
-  ICOC Meeting
-  Industry Meeting

In order to obtain ICOC (Board) and external stakeholder perspectives regarding the draft 2012 Strategic Objectives, the CIRM leadership team met with distinct stakeholder groups in five cities across California.



**USC:** Tuesday, October 25  
(Public Meeting)



**UCI:** Wednesday, October 26  
(ICOC Board Meeting)



**Sanford Cons. SD:** Thursday,  
October 27 (Industry Meeting)



**ELAN:** Friday, October 28  
(Industry Meeting)



**UCSF:** Monday, October 31  
(Public Meeting)

*At each meeting, CIRM leadership provided an overview of progress to date and the proposed changes to the 2012 Strategic Objectives before seeking stakeholder input through a facilitated discussion.*

## Stakeholder Input

### Key themes

1	<b>Established Momentum</b>	CIRM has made great initial progress in establishing an extensive program in support of stem cell research and the advancement of science.
2	<b>Sustainability</b>	CIRM needs to become more aggressive in finding alternate funding resources and to implement greater creativity in identifying the types of organizations that may be able to contribute to the sustainability of CIRM's work.
3	<b>Communication/ Public Awareness</b>	Robust public affairs tactics are necessary, and CIRM needs to better communicate the organizational initiatives, as well as educate the public more broadly.
4	<b>Global Networking</b>	CIRM needs to provide greater opportunities for networking and breed collaborative projects that unite academia and industry, as well as researchers across geographic regions.
5	<b>Process Optimization</b>	Greater transparency in the funding process is needed, and there is a great need for the process to be less bureaucratic and easier to navigate.

## ICOC (Board) and Stakeholder Input Overarching Recommendations

- Public Meeting
- ICOC Meeting
- Industry Meeting

ICOC (Board) and Stakeholder input relative to each strategic objective, rolled this information up to provide a summary of considerations for the CIRM leadership team.

		Strategic Objectives			
		Scientific	Medical	Economic	Social
ICOC (Board) and Stakeholder Type	Public Input	<ul style="list-style-type: none"> <li>▪ Focus on imaging sciences</li> <li>▪ Create disease “hubs”</li> <li>▪ Share “lessons learned”</li> </ul>	<ul style="list-style-type: none"> <li>▪ Facilitate partnership opportunities</li> <li>▪ Obtain a cure or pass a major milestone</li> <li>▪ Consider surgery and somatic cell nuclear transfer</li> </ul>	<ul style="list-style-type: none"> <li>▪ Create funding opportunities</li> <li>▪ Find funding partners</li> <li>▪ Create three-way agreements</li> <li>▪ Allow project flexibility</li> </ul>	<ul style="list-style-type: none"> <li>▪ Ensure public awareness</li> <li>▪ Educate high school teachers/students</li> <li>▪ Simplify presentations</li> <li>▪ Create apps</li> <li>▪ Create CIRM image/logo</li> </ul>
	ICOC Input	<ul style="list-style-type: none"> <li>▪ Consider sustainability</li> </ul>	<ul style="list-style-type: none"> <li>▪ Require bi-directional communication</li> <li>▪ Categorize promising areas of research</li> <li>▪ Reduce threshold towards translational research</li> <li>▪ Define success</li> <li>▪ Learn from others</li> </ul>	<ul style="list-style-type: none"> <li>▪ Create matrix to funding platform</li> <li>▪ Engage and partner with HMOs</li> <li>▪ Include sustainability objective to strategic objectives</li> </ul>	<ul style="list-style-type: none"> <li>▪ Promote CIRM’s work</li> <li>▪ Involve national stakeholder groups</li> <li>▪ Create list of statistics on disease and cost</li> <li>▪ Tailor strategies for various audiences</li> <li>▪ Create apparatus for “stars” (i.e., “star” patients, researchers) to shine</li> </ul>
	Industry Input	<ul style="list-style-type: none"> <li>▪ Share “lessons learned”</li> </ul>	<ul style="list-style-type: none"> <li>▪ Create communication bridges</li> <li>▪ Split review process (academic vs. industry)</li> <li>▪ Teach core processes</li> </ul>	<ul style="list-style-type: none"> <li>▪ Better communicate the details of the funding process</li> <li>▪ Create a shorter approval process</li> <li>▪ Create CIRM “champion” role(s)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Identify and promote CIRM’s expertise</li> <li>▪ Educate patients on stem cell facilities as well as stem cell medicine</li> </ul>



## Public Meetings

### Recommendations and Feedback

During each of the public meetings, participants provided specific recommendations and valuable feedback to the CIRM leadership team across all four draft strategic objectives.

Public Meetings			
Scientific	Medical	Economic	Social
<ul style="list-style-type: none"> <li>Focus on imaging sciences to <i>track</i> the stem cells, to guide research, show to regulatory bodies</li> <li>Create disease “hubs” to promote synergy of research efforts between research groups</li> <li>Facilitate forums for researchers to discuss and share “lessons learned”</li> </ul>	<ul style="list-style-type: none"> <li>Facilitate partnership opportunities for academia and industry early</li> <li>Obtain a cure or pass a major milestone towards one</li> <li>Consider that stem cell therapy could help reduce the need for invasive surgery</li> <li>Consider somatic cell nuclear transfer</li> </ul>	<ul style="list-style-type: none"> <li>Create opportunities for funding organizations to discuss revenue generation (MCOs, industry, private, VC)</li> <li>Create agreements with academic centers, industry and CIRM – multi-party agreements</li> <li>Find funding partners so CIRM becomes a catalyst, rather than sole funder</li> <li>Allow more flexibility in the types of projects funded</li> </ul>	<ul style="list-style-type: none"> <li>Ensure general public is aware of CIRM’s scientific efforts and funding allocations</li> <li>Educate high school teachers/ students on stem cell research (e.g., PBS series)</li> <li>Simplify presentations into “plain” English rather than scientific jargon</li> <li>Create applications (Angry Birds!) and use social media to educate “average” person</li> <li>Create an image/logo for CIRM and associate it with San Francisco</li> </ul>

## ICOC Board Meeting

### Recommendations and Feedback

During the ICOC board meeting, participants provided specific recommendations and valuable feedback to the CIRM leadership team.

ICOC Board Meeting			
Scientific	Medical	Economic	Social
<ul style="list-style-type: none"> <li>Consider sustainability—we need to do enough to attract others to the field for continuity</li> </ul>	<ul style="list-style-type: none"> <li>Require bi-directional communication with labs regarding what works and what doesn't</li> <li>Categorize "fast-moving" areas where CIRM can get quickest results to show to public</li> <li>Define "success" as passing major milestones toward a cure, not necessarily as a cure itself</li> <li>Reduce the threshold from scientist's idea to actual translational research</li> <li>Learn what other companies have ready to move forward (e.g., w/o RFPs)</li> </ul>	<ul style="list-style-type: none"> <li>Create "matrix" to capture our funding platform overlaid with therapeutic areas, mechanisms of action, and technologies used—see the big picture</li> <li>Need "Sustainability" objective to guide where we'll be with funding down the road</li> <li>Engage MCOs (e.g., Kaiser, Medicaid) early</li> <li>Need to partner with BlueCross, Anthem, Kaiser, and Medicaid to communicate our work and perhaps get funding</li> </ul>	<ul style="list-style-type: none"> <li>Promote CIRM's work by establishing as household word; need to be on TV, net; need to have omnipresence</li> <li>Involve every national stakeholder, biomed group, and research advocacy group</li> <li>Tailor strategies for various audiences</li> <li>Need accurate list of statistics (i.e., cost of total diseases) so that every advocate could use them</li> <li>Create an apparatus for "stars" (i.e., "star" patients, researchers) to shine; need to highlight stories</li> </ul>

## Industry Meetings

### Recommendations and Feedback

During each of the industry meetings, participants provided specific recommendations and valuable feedback to the CIRM leadership team across all four draft strategic objectives.

**Industry Meeting**

Scientific	Medical	Economic	Social
<ul style="list-style-type: none"> <li>▪ Focus on how to take learnings from successful projects and applications and communicate to new applicants</li> </ul>	<ul style="list-style-type: none"> <li>▪ Act as a bridge between academia and big pharma to facilitate education on where the road blocks are and brainstorm on possible projects/partnerships</li> <li>▪ Actively facilitate communication between US and ex-US based companies to support possible projects</li> <li>▪ Consider splitting the review process for academic vs. industry applications</li> <li>▪ Facilitate discussion of the commercialization process earlier in development</li> </ul>	<ul style="list-style-type: none"> <li>▪ Better communicate the areas and overall funding mechanism process</li> <li>▪ Create a less bureaucratic, shorter approval process for funding; companies have a burn rate that CIRM needs to be aware of</li> <li>▪ Increase flexibility for funding (e.g., translational research, not just early research)</li> <li>▪ Provide a “champion” for industry partners to help navigate the CIRM funding process</li> </ul>	<ul style="list-style-type: none"> <li>▪ Identify three to four things in which CIRM is the leader and articulate this to the world</li> <li>▪ Help patients better understand what they should look for when they go to stem cell facilities (e.g., what to avoid in less conscientious centers) or attract to Californian centers</li> <li>▪ Educate patients by leveraging clinic networks</li> </ul>
	<ul style="list-style-type: none"> <li>▪ Teach academic researchers the core processes on what it will take to get into clinic (e.g., terminology, processes, translational studies, GLP/GMP capabilities)</li> </ul>	<ul style="list-style-type: none"> <li>▪ Change the currently strong perception that grants are academically focused</li> <li>▪ Consider VC partnerships</li> <li>▪ Create “alpha centers” for payer negotiations</li> </ul>	

## Industry Advisors

### Recommendations and Feedback

**During a meeting on November 10<sup>th</sup> industry advisors focused on the definition of success and portfolio management, CIRM’s loan program, co-funding requirements, translational support programs, and the suggestion of a Pharma summit.**

Primary suggestions for CIRM included: Concentrate on getting the best projects through early clinical trials; CIRM will be judged successful if a number of its funded programs are in clinical trials, preferable through early clinical proof of concept in people; Focus on portfolio management to ensure CIRM’s best programs obtain the essential continued financial support through early clinical proof of concept in people; CIRM needs to cut programs that are not performing; CIRM should use forecasting and decision analysis, using professional advice, to shape its future funding programs and determine how many programs CIRM can support through the clinic. Advisors recommended the loan program should be simplified (perhaps a loan + royalty)

and flexible so that companies can decide what type of program best fits their needs.

Emphasized that Pharmas will want CIRM to de-risk projects, and commit to co-funding of projects at the earlier stages of development until such programs have a little less risk; suggested virtual management teams available to academic start up teams, and suggested a Pharma summit may be a good way to inform Pharma of what CIRM is funding and possibly attract co-funding.

## **Collaborative Funding Partners (CFP)**

### Recommendations and Feedback

**During each of the 2 telecons with CFPs – November 15<sup>th</sup> with Japan, Australia and India; November 18<sup>th</sup> with Canada, Germany, Maryland, Scotland, Juvenile Diabetes Research Foundation, and the National Institutes of Health, the CFPs provided feedback and suggestions to strengthen, enhance collaborations.**

This included the development of a Capability map to show strengths, expertise across the different CFPs; interest in forging multi-CFP collaborations with CIRM; desire to have more input into the development of Concepts for RFAs; interest in harmonizing material transfer agreements (MTAs) and informed consents where possible, and interest in forging partnerships for clinical trials.

## **Alliance for Regenerative Medicine (ARM)**

### Recommendations and Feedback

**Telecons on November 21<sup>st</sup> with leaders of ARM focused on the strategic objectives.**

For the strategic objective “Social”, recommended CIRM focus on a broader message, including: value of CIRM; value of regenerative medicine; the value of the regenerative medicine that CIRM funds, working towards a national strategy for regenerative medicine, and being more explicit about the intent to engage regulators, payors and Congress to advance science into the clinic, and suggested the development of metrics for measuring social impact. For the strategic objective “Economic” suggested adding follow-on investment and financial support for the most promising of the CIRM funded projects, and suggested changing the “Medical” strategic objective label to “Clinical.” From their perspective, noted the legislature and public will not define success as seeding the field and building facilities, but in showing that CIRM has therapies in development.

**Next Steps - Over the next few months the CIRM leadership team, working closely with the ICOC, will need to take the inputs from the stakeholder meetings and embed them into the 2012 Strategic Plan.**

2011	2012
<p><b>September 19–December 5</b> ✓ Collect stakeholder feedback through public and invitational meetings and conference calls</p> <p><b>December 8 ICOC/Board Update</b></p> <p><b>December 20</b></p> <ul style="list-style-type: none"><li>▪ First revision to senior management</li></ul>	<p><b>January 3</b></p> <ul style="list-style-type: none"><li>▪ Second revision to broader staff</li></ul> <p><b>January 17</b></p> <ul style="list-style-type: none"><li>▪ Third revision to ICOC/Board for input</li></ul> <p><b>February 15</b></p> <ul style="list-style-type: none"><li>▪ ICOC/Board comments back to senior staff</li></ul> <p><b>March 21</b></p> <ul style="list-style-type: none"><li>▪ Final version ready for ICOC/Board vote</li></ul>

✓ Completed activity