

Update on Management's Response to the Performance Audit

Rafael Aguirre-Sacasa, J.D.

General Counsel

ICOC Meeting

September 26, 2024



Our Mission

Accelerating world class science
to deliver transformative
regenerative medicine treatments
in an equitable manner to a
diverse California and world.





Agenda

1. 2022-'23 Performance Audit – Management's Response
2. 2019-'20 Performance Audit – Management's Response

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations



FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Leadership	
Finding #1	Eleven staff members currently report directly to CIRM’s Chief Executive Officer (CEO), versus the industry standard of four to six, which presents a risk to the capacity of the executive role.
Recommendation	Alongside the search for a new CEO, explore organizational structure options to reduce the CEO’s span of control and align similar functions.
Action by CIRM	<p>The CEO is evaluating the current reporting structure of the Leadership Team and CIRM as a whole.</p> <p>As part of the reorganization, the CEO has created the positions of VP Operations, Chief Science Officer, Executive Strategy Officer - Rare Diseases, and Associate VP of Preclinical Development, and streamlined the decision-making structure by creating a 5-member Executive Team (CEO, CSO, VP Ops, VP Review, and GC). The number of direct reports to the CEO has been reduced from 12 to 8.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Leadership	
Finding #2	The Independent Citizens’ Oversight Committee (ICOC) is large, comprising 35 members, and meetings are held in a hybrid environment. Both of these factors present potential risk to full board engagement and productivity.
Recommendation	<div>A. Regularly assess hybrid meeting practices, board member engagement, relationships among board members, and meeting effectiveness to identify opportunities for continuous improvement. Consider implementing procedures to encourage meaningful dialogue in ICOC meetings while balancing the time required to discuss agenda items.</div> <div>B. Continue to leverage committees and working groups to engage board members and conduct in-depth governance responsibilities at the committee level.</div>
Action by CIRM	<p>CIRM leverages the important work of the Board’s subcommittees and working groups to provide robust policy analysis and development, which efforts continue. In addition, CIRM will work with the Board Governance team to conduct an engagement survey of the board to identify specific areas of opportunity for further engagement. Extra effort is now being given post-Covid to encourage in-person attendance at board meetings (5/year) and provide the opportunity to engage the CIRM team outside of such meetings. To provide greater transparency and insight to CIRM’s work, CIRM will develop with Board Governance a series of small-group primers on key policies and activities for board members. A test-case involving IP policy development has demonstrated value and will be scaled up in the coming year.</p> <p>Extra effort is being given to encourage in-person attendance at full board meetings (4-5/year to be situated in Northern and Southern California) and provide the opportunity to engage the CIRM team outside of such meetings. The BG team conducted a survey in March 2024 to identify ways to improve board member experience and are in the process of addressing points raised in the surveys, e.g., developing an intuitive extranet, taking greater effort to inform all members of monthly activities of the Board and CIRM overall along with directed communication related to CIRM efforts closer to members’ areas of residence. BG and the CIRM team are also developing a series of small-group primers on key policies and activities for Board members.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Operations	
Finding #3	Although sampled sole-source procurements complied with CIRM policies, Fi\$Cal system limitations resulted in CIRM inconsistently recording sole-source contracts within the procurement module, leading to opportunities to improve contract recording and enhance transparency in the sole-source contract monitoring process.
Recommendation	<ul style="list-style-type: none">A. Develop a process to ensure sole-source contracts are consistently recorded in Fi\$Cal for reporting purposes.B. As a best practice, the Responsible Administrative Official's biannual report to the Governance Subcommittee and annual report to the Governing Board should be updated to increase transparency in sole-source processes given CIRM's reliance on these contract types.
Action by CIRM	<p>In consultation with Fi\$Cal, the Finance team has identified and implemented a new process whereby sole source contracts are recorded consistently with Fi\$Cal. Management already discloses sole source contracts to the Board as part of the contract reports. Moving forward sole source contracts will be specifically identified in the contracts report.</p> <p>Sole source contracts are now identified as such in the contracts report provided to the ICOC every 6 months.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Operations	
Finding #4	CIRM's Loan Election Policy, located within the Grants Administration Policy for Clinical Stage Projects, contains references to outdated information that would impact the terms of a potential loan.
Recommendation	<ul style="list-style-type: none">A. Ensure that the Loan Election Policy is comprehensive and no longer references the outdated CIRM regulation 100801 to ensure requirements are up to date.B. Replace references to the London Interbank Offered Rate (LIBOR) in CIRM regulations with an alternative benchmark such as the Secured Overnight Financing Rate (SOFR).
Action by CIRM	<p>There is currently a LIBOR reference in the CLIN Grants Administration Policy (GAP). CIRM plans to revise the CLIN GAP to replace LIBOR with another index and to make other updates as recommended. In the meantime, we are permitted under the GAP to utilize another index if it is so stipulated in a grantee's Notice of Award. Accordingly, we plan to use the Secured Overnight Financing Rate ("SOFR") instead of LIBOR in NOAs moving forward.</p> <p>We are using the Secured Overnight Financing Rate ("SOFR") instead of LIBOR in NOAs. This will be codified in the next update to the Grants Administration Policy scheduled for later this fiscal year.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Operations	
Finding #5	CIRM's monitoring of grantee compliance with technology disclosure requirements, outlined in CIRM's Intellectual Property and Revenue Sharing Requirements for Non-Profit and For-Profit Grantees, continues to be largely ad hoc, which can create risk of noncompliance and negatively impact revenue sharing.
Recommendation	Continue to submit disclosure surveys to awardees on a recurring basis (e.g., triennially), and consider the development of a risk-based audit program to ensure appropriate reporting of technology disclosures.
Action by CIRM	<p>Based on discussions with Moss Adams, in FY 22-23, CIRM conducted an initial survey of CLIN level grants to identify applicant projects associated with CIRM grants that have been licensed or commercialized. CIRM received responses from over 60% of grantees. CIRM plans on implementing the survey triennially and to expand it to include TRAN awards.</p> <p>The Legal team is following up with the non-responders (22%). Any non-responder will be ineligible for any CIRM funding until such deficiencies are remedied.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Planning & Program Development	
Finding #6	CIRM is in the process of developing and launching the Patient Support Program (PSP), which has inherent uncertainty related to financial sustainability of the Patient Assistance Fund (PAF), anticipated number of patients served, and program duration.
Recommendation	As CIRM implements the PSP, it should conduct regular reporting to the ICOC on the number of patients served and average cost per patient as well as develop a data-informed evaluation of the PSP's possible reach and duration.
Action by CIRM	Reporting these performance metrics is a requirement in the PSP application. Specific operational details will be part of the business rules/reporting process to be agreed upon with the successful applicant. This data will also be provided to the AAWG, so they can provide recommendations for reach and duration. Reporting these performance metrics is a requirement in the PSP application. Specific operational details will be part of the business rules/reporting process to be agreed upon with the awardee (Eversana). This data will also be provided to the AAWG, so they can provide recommendations for reach and duration.

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Planning & Program Development	
Finding #7	CIRM collects considerable amounts of data that is valuable to stem cell and regenerative medicine researchers. However, it has not established a data governance structure or process to collect, compile, or share this data, which would help advance its mission.
Recommendation	Establish a data governance structure to capitalize on the reporting from grantees and facilitate data sharing capabilities for stem cell and regenerative medicine researchers.
Action by CIRM	<p>CIRM will develop a data infrastructure framework for CIRM <u>research</u> data. This includes full implementation of data sharing and management plan guidelines for all CIRM’s research awards and the development and deployment of a public metadata dashboard for CIRM-funded data.</p> <p>CIRM is developing a comprehensive data infrastructure framework for all research data. This includes the deployment of a metadata dashboard, scheduled for production by the end of September 2024, and the launch of online Data Sharing and Management Plans (DSMPs) that have been implemented for all Discovery awards. Existing DSMPs and 172 additional datasets from older grants have been digitized, with the potential for further data expansion as funding allows. Additionally, through the recent organizational reorganization, CIRM has established a dedicated data infrastructure function to lead and manage these initiatives, ensuring streamlined data sharing, standardized terminology, and enhanced collaboration among stakeholders.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Planning & Program Development	
Finding #8	As CIRM revived its operations and added new programs, leadership restructured some functions, which impacted workload distribution within and among teams. This has resulted in elevated workloads for specific groups of employees, which will likely continually evolve alongside CIRM's area of focus.
Recommendation	Incorporate a data driven workload analysis that includes realistic timelines and staffing needs into annual operational planning to promote right sized workloads among CIRM employees.
Action by CIRM	<p>The Human Resources team is working with the Leadership Team and managers on setting expectations re: timelines and proper staffing levels to support CIRM's operational requirements and goals.</p> <p>Following the recent reorganization, which includes HR now reporting to the CEO, the HR and the leadership teams will evaluate job duties to ensure workloads are appropriate and make necessary adjustments. Realistic, manageable timelines will be set based on team capacity. If staffing gaps are identified, we may use temporary employees or contractors or permanent hires, supported by a recruitment plan to meet workload demands.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Planning & Program Development	
Finding #9	The pace of programmatic and operational changes at CIRM has led to challenges for staff in maintaining an understanding of priorities, workstreams, and awareness of agency operations.
Recommendation	<ul style="list-style-type: none">A. Adopt a standardized change management template and promote communication and accountability throughout all change processes.B. Create a culture of deliberate change management to ensure new programs and initiatives are effectively communicated, implemented and adopted.
Action by CIRM	<p>The Leadership Team is reviewing options for Change Management consulting to help identify organizational gaps in order to implement best practices and training for the staff.</p> <p>The HR Team has created a Standardized Organizational Change Management process to promote communication and accountability through internal alignment on the type and extent of any upcoming changes. This is done by setting goals, defining how organizational structures and roles will shift, and getting buy-in from any stakeholders. In addition, the HR team has held meetings with the affected employees to discuss roles and scopes of responsibilities and answer any questions.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Human Resources	
Finding #10	CIRM has historically relied on manual and undocumented Human Resources (HR) processes, with minimal employee self-service options.
Recommendation	<div>A. Continue to pursue HR process automation and employee self-service opportunities through the full integration of BambooHR.</div> <div>B. Document key HR procedures in a centrally available location to ensure accessibility and consistency for CIRM employees.</div>
Action by CIRM	<p>The Human Resources (HR) team is revising out-of-date policies and procedures as well as drafting new policies where there are gaps. Certain policies (e.g., revised Compensation Policy) will be presented to ICOC for approval. In 2023, HR implemented Cal Employee Connect for timesheet automation (vs. prior manual process) that ties into the payroll data produced by State Controllers Office and CalLearns for for online employee training/professional development.</p> <p>New Compensation and Relocation Policies were approved by the ICOC on June 27, 2024. HR is working with IT to create an HR Intranet Portal which will provide employees with easy access to HR policies and procedures, employee benefits information, training and other relevant HR materials. HR also provides employees self-service training options such as Cal Learns.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Human Resources	
Finding #11	Limited HR policy documentation, constrained HR personnel, and significant hiring needs following Proposition 14 approval resulted in delayed hiring and inconsistent new employee onboarding and training.
Recommendation	Develop and document standard operating procedures (SOPs) for hiring and onboarding process to promote a consistent experience. Where appropriate, differentiate onboarding plans for varying employee types to ensure the provision of appropriate information and training for new employees.
Action by CIRM	<p>We hired a new Director of HR in 2023 and HR now has 2 FTE and 2 RAs. As part of its refresh of the HR Policies and Procedures, the HR team has standardized and streamlined the hiring and onboarding processes in order to promote a more consistent experience for new employees. The hiring process has been documented and is now done via BambooHR (new online HR platform). The revamped process has reduced hiring times from an average of 4-6 months to less than 2 months. HR has also begun doing pre-start date meetings to go over benefits and the perks of State service.</p> <p>HR has reviewed and revised CIRM's hiring and onboarding processes.</p>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Human Resources	
Finding #12	Due to historical compensation practices, pay inequities may have developed between tenured and new employees.
Recommendation	<div>A. Complete revision of the compensation policy to prevent future instances of pay inequity.</div> <div>B. In alignment with the new compensation policy, examine existing pay inequities among employees and develop a plan to remedy them as appropriate.</div>
Action by CIRM	<div>The Human Resources team has reviewed and revised CIRM’s Compensation plan and positional salary levels. These updates will be presented to the ICOC for approval.</div> <div>The ICOC reviewed and approved a new Compensation Policy and updated positional salary levels on June 27, 2024.</div>

FY 2022–2023 PERFORMANCE AUDIT

Findings and Recommendations

Human Resources	
Finding #13	Many CIRM employees question the efficacy and consistent application of the current hybrid work policy, which may hinder productivity and employee morale.
Recommendation	<ul style="list-style-type: none">A. Evaluate the impact of CIRM’s work from home (WFH) policy on employee productivity and determine the degree to which it is applied consistently and supports operational goals.B. Consider creating and documenting allowable exceptions to the WFH policy to support consistent application and transparency in how hybrid work is applied across teams.
Action by CIRM	<p>CIRM’s Telework Policy has been revised and updated to reduce inconsistencies in applicability while fostering greater employee engagement and collaboration by instituting multiple “anchor days” per week when employees are expected to be in the office physically. The “anchor” days provide collaboration among staff, leading to productivity, thus supporting operational goals.</p> <p>Employee feedback supports the updated Telework Policy.</p>

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations



FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Compliance	
Finding #2b	During testing of the grants management process, we identified three exceptions to the Grants Administration Policy Standard Operating Procedures (SOPs) in a sample of 20 grants in process, 23 new grants, and 20 closed grants.
Recommendation	B. Consider adding a requirement for a separate individual to review due dates entered in the GMS to ensure there are no data entry errors and to prevent late reports due to these errors.
Action by CIRM	The three exceptions identified were related to two grants under the EDUC1: Conference Grant program. As of 2022, the following improvements have been made: 1) Created a Conference Grant progress report type in the grants database that is approved by both the GM and the Science Officer. 2) Automated the Contract Amendment template to include pre-populated data from the GMS 3) Updated the GM SOP with a compliance check evaluation by Director of GM on all Amendments to NOAs. Completed.

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Compliance	
Finding #3	CIRM adopted regulations in 2018 outlining the technology disclosure requirements. While we found no exceptions, we noted that the ability for CIRM to monitor and determine compliance of the Grantees with the technology disclosure appeared challenging.
Recommendation	Implement an IT control that allows for missing documentation or reports to be flagged and routed to the responsible CIRM team members.
Action by CIRM	CIRM initially implemented an IT control for flagging missing documentation or reports but the method used did not result in the desired outcomes. Instead, after consultation with Moss Adams, CIRM implemented the aforementioned survey of CLIN level grants to identify applicant projects associated with CIRM grants that have been licensed or commercialized. See slide 9, above.

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Efficiency and Effectiveness	
Finding #6b	CIRM does not have an effective policy or proactive process for monitoring and enforcing awardee publication disclosures.
Recommendation	Consider options, such as implementing a Customer Relationship Management (CRM) system, to support automated proactive monitoring of awardee publication and press releases.
Action by CIRM	<div>A. Publication disclosures are required as part of awardee reporting requirements and the program teams are closely monitoring submissions. CIRM policy will withhold funds in the absence of complete reporting.</div> <div>B. CIRM has evaluated 3rd party solutions to track publications but has not yet found a suitable solution. We will continue looking at other options.</div> <div>CIRM’s Software Development Team has identified three potential CRM vendors and will have made a final decision by early October 2024.</div>

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Efficiency and Effectiveness	
Finding #7	CIRM has historically relied on scientific experts and partners with a connection to the organization for grant review. As a public agency with the mission of cures for all, it is important for CIRM to diligently seek diverse perspectives and expertise and ensure the perception of independence in application review.
Recommendation	Continue to implement recently adopted practices to actively seek more diverse members of the California scientific community to review and recommend grants, and monitor and evaluate the Grants Working Group (GWG) to promote a diversity of perspectives, backgrounds, and expertise.
Action by CIRM	<p>CIRM has launched an organization-wide DEI initiative and engagement with subject matter experts dedicated to assess and encourage diversity among the GWG. In addition, the Leadership Team is reviewing the DEI strategy for the entire organization.</p> <p>CIRM has partnered with expert DEI consultants to assess and encourage diversity among the GWG. CIRM has received recommendations from our DEI consultants, provided training to GWG members, continued to solicit feedback from board members, and made efforts to recruit new GWG members that diversify the skills and experience of our expert review panels.</p> <p>Additionally, CIRM is preparing an RFP for additional consulting services with the goal of retaining advisors to help CIRM assess its internal DEI protocols make recommendations for strengthening these protocols.</p>

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Finance	
Finding #8	CIRM's Records Retention Schedule with the State of California expired in 2018. Staff continue to report confusion related to records retention requirements, which can negatively impact the organization's ability to respond to information requests.
Recommendation	CIRM should update its Records Retention Schedule, establish policies and procedures for records management, and consider developing annual trainings to support a consistent understanding of records requirements.
Action by CIRM	The State Secretary of State Records and Information Management Division provided training to CIRM's staff on March 23, 2022. Select CIRM staff completed Records Management Training and certification. CIRM sent an updated Records Retention Schedule to the Secretary of State in September 2022. The Secretary of State provided feedback on the initial submission and CIRM has since replied with an updated Records Retention Schedule.

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Efficiency and Effectiveness	
Finding #9	The use of three document management systems continued to present confusion to CIRM employees, resulting in inconsistent user adoption and records management practices.
Recommendation	When implementing a new document management system, develop an adoption strategy that includes ample communication, policy and procedure guidance, and accountability practices to support consistent expectations and system utilization.
Action by CIRM	<p>CIRM staffs a small (3 FTE) IT department with contractor partners. Due to the departure of the Director of IT in '22-23, CIRM delayed the implementation of a new document management system to keep other critical projects, such as the technology build-out of CIRM's HQ and bringing State Payroll systems in-house, on track. With a new Associate Director (AD) of IT as of 11/22, the CIRM team has performed a needs assessment, piloted solutions and selected Microsoft Office 365 for an integrated document management platform for staff. The AD has built an adoption strategy which will be implemented by the end of calendar year 2024.</p> <p>As of September 30, 2024, the IT department will have fully migrated to Microsoft Office 365 and SharePoint.</p>

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Efficiency and Effectiveness	
Finding #10	CIRM has made significant improvement to the Grants Management System (GMS) in recent years; however, additional opportunities exist to leverage the GMS to improve operational efficiency and effectiveness.
Recommendation	Continue to identify and pursue opportunities to enhance GMS capabilities to automate processes, centralize data, and enhance access.
Action by CIRM	<p>With the departure of the Director of IT who created CIRM's Grants Management System, CIRM management engaged a consultant to evaluate the future of CIRM's grants database and perform a needs assessment. The consultant recommended that CIRM continue with the in-house Grants Management System as it is technologically stable and well-integrated into CIRM's unique operations and provided a roadmap for evolving the system. CIRM's Software Development team has begun implementing these recommendations, starting with the system performance improvements and enhanced reporting solutions.</p> <p>The Software Development team has completed the software performance and security audit. The Grants Management System is undergoing significant improvements in terms of performance, robustness and data integration for reporting. The performance and robustness work takes place on an ongoing basis and has already resulted in increased user satisfaction and evidence of improved throughput (e.g., long-running reports). For analytics, there is a separate project to integrate GMS data into Microsoft PowerBI, and this has resulted in improved ad-hoc reporting capabilities and dashboarding.</p>

FY 2019-2020 PERFORMANCE AUDIT

Findings and Recommendations

Efficiency and Effectiveness	
Finding #11	CIRM hosts a significant amount of scientific and business data but lacks a strategy or system to integrate information in an optimal way.
Recommendation	Consider implementing an integrated database and Customer Relationship Management (CRM) system to collect and better analyze scientific and business data in support of CIRM's mission.
Action by CIRM	<p>Due to the departure of the Director of IT, CIRM had to delay the implementation of a CRM to keep other critical projects, such as enhancing CIRM's cybersecurity program, on track. With a new Associate Director (AD) of IT onboarded as November 2022, the CIRM team has begun evaluating CRM solutions that integrate with other adopted solutions at CIRM to select one by end of FY 23-24 with the goal to complete full organization implementation and adoption by the end of FY 24-25.</p> <p>The IT team completed its annual cybersecurity penetration test resulting in no major findings and has drafted a cybersecurity policy that is being reviewed internally by the Executive Team.</p> <p>CIRM's Software Development Team has identified three potential CRM vendors and will have made a final decision by early October 2024.</p>



Thank You



CONTACT US

(510) 340-9101

INFO@CIRM.CA.GOV

601 GATEWAY BLVD, SUITE 400
SOUTH SAN FRANCISCO, CA 94080

CIRM.CA.GOV