

PRIORITIZATION / STRATEGIC ALLOCATION FRAMEWORK OVERVIEW

| | |
|---|---|
| 1 – EXECUTIVE SUMMARY | 1 |
| 2 – BACKGROUND & RATIONALE | 1 |
| A. Current Financial Overview for CIRM | 2 |
| B. Scope of CIRM Funding | 2 |
| C. Landscape of Regenerative Medicine | 2 |
| D. Finite Resources and Increasing Demand | 3 |
| 3 – CIRM’S IMPACT TO DATE | 3 |
| 4 – STRATEGIC ALLOCATION FRAMEWORK..... | 4 |
| 5 – NEXT STEPS | 4 |
| 6 – TIMELINE | 5 |

1 – EXECUTIVE SUMMARY

The California Institute for Regenerative Medicine (CIRM) has established itself as a leader in propelling stem cell research and regenerative medicine, dedicated to accelerating scientific discoveries into transformative treatments. Since its establishment, CIRM's contributions have been vast, funding vital research, bolstering infrastructure development, implementing and advancing educational initiatives, and facilitating the discovery and development of regenerative medicine therapies. Yet, with the rapid evolution of the regenerative medicine field, CIRM is presented with a pivotal challenge: the strategic allocation of limited resources across a spectrum of initiatives to optimize impact and further propel the field.

To enhance the efficacy of its funding strategy, CIRM's approach to resource allocation is more crucial than ever. We must consider the current balance of available funds for research programs and review historical allocations to inform the development of potential scenarios for resource utilization. This process is compounded by the reality that the demand for funding greatly exceeds the available resources.

This document provides a framework by defining the rationale, objectives, scope, process, and timeline that are needed to delineate CIRM’s strategic allocation.

Ultimately, strategic prioritization for CIRM is a testament to the institute's profound dedication to its mission—transforming healthcare through the power of regenerative medicine.

2 – BACKGROUND & RATIONALE

In preparation for the upcoming discussions, an overview of CIRM’s budget allocations and remaining funds for funding initiatives and programs is presented. This figure will be central to our discussions on continued implementation of CIRM’s strategic plan and prioritization for future research endeavors and funding allocations.

A. Current Financial Overview for CIRM



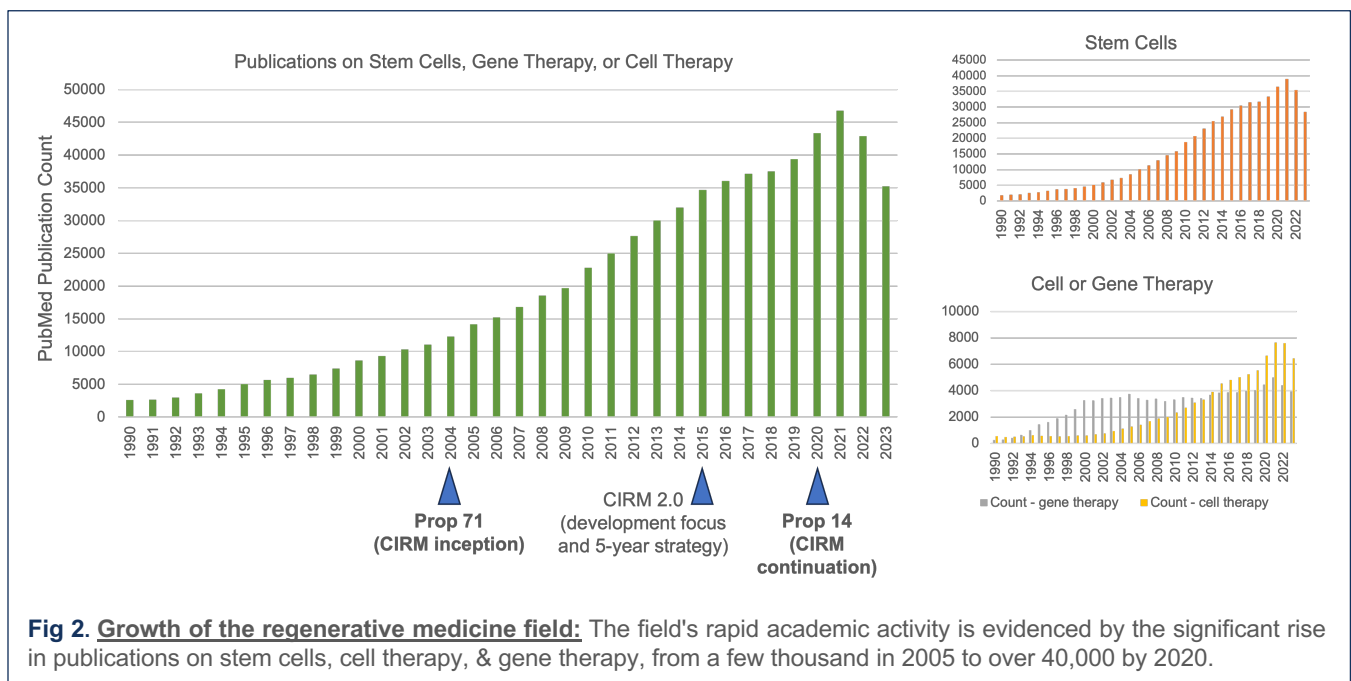
B. Scope of CIRM Funding

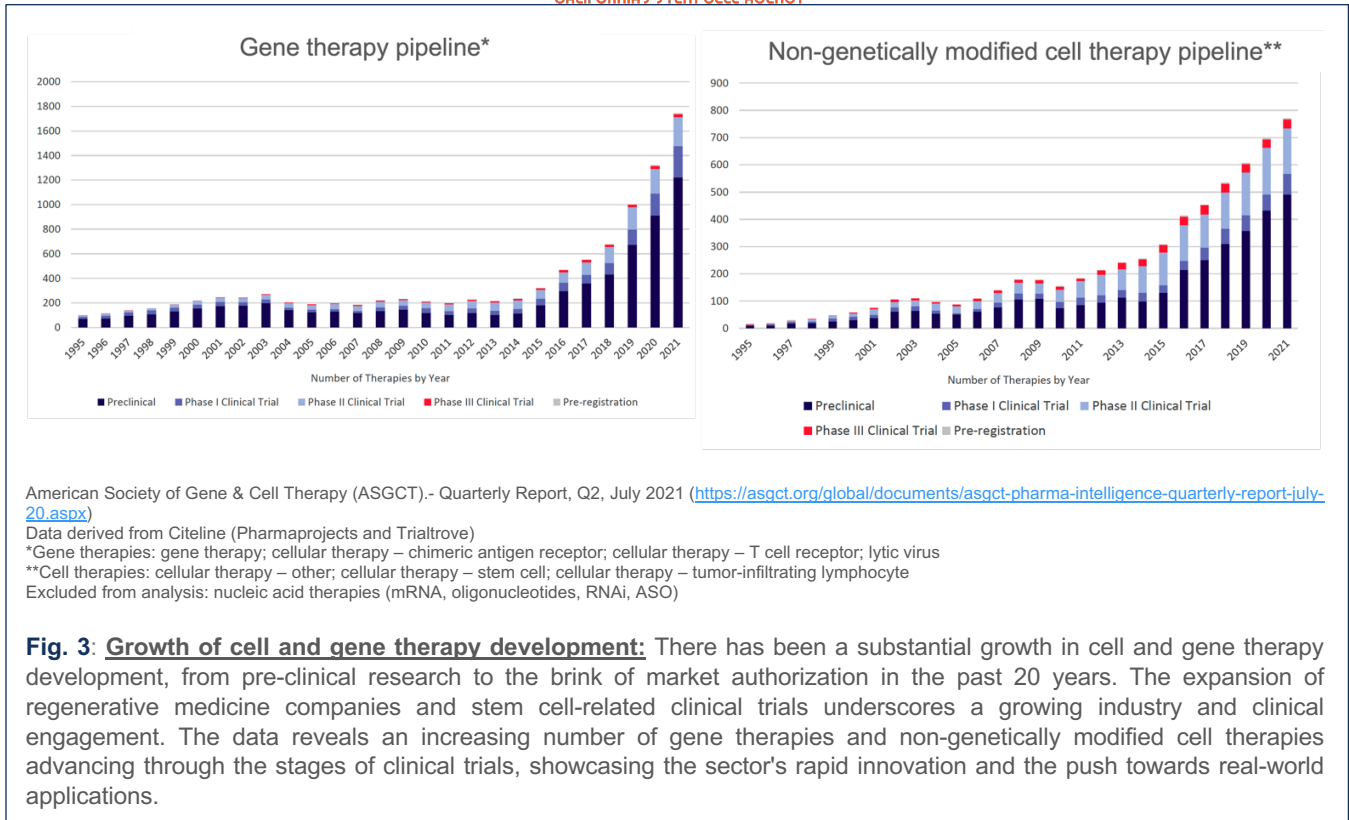
As we prepare to discuss the strategic prioritization of the approximately \$3.54B in available funds, it is important to delineate its scope. CIRM's mandate directs us to concentrate on research using stem and progenitor cells, as well as genetic research and genetic therapies, particularly in areas that are not generally supported by the NIH and the Federal Government.

As we enter this new phase of implementing CIRM's strategic plan, our focus should be on identifying and supporting projects that will cement CIRM's long-term impact over the next decade. In doing so, we face the challenge of balancing a diverse portfolio of investments while directing a concerted effort toward unique and high-potential opportunities. This strategic funding allocation will ensure that CIRM not only contributes to the current landscape of regenerative medicine but also shapes its future.

C. Landscape of Regenerative Medicine

The landscape of regenerative medicine is marked by an accelerating pace of scientific breakthroughs (Fig. 2 & Fig.3), the emergence of innovative therapeutic products, and an expanding array of clinical trials targeting a wide spectrum of diseases and injuries. This dynamic environment presents both opportunities and challenges for funding bodies like CIRM.





D. Finite Resources and Increasing Demand

Despite the promise and progress in regenerative medicine, CIRM's resources are finite. The demand for funding significantly exceeds available financial resources, necessitating a strategic approach to allocation. This scenario underscores the importance of prioritizing investments in areas where CIRM can have the greatest impact.

3 – CIRM'S IMPACT TO DATE

CIRM's impact to date has been realized through strategic investments in a wide array of initiatives that interoperate together to realize our mission. Until now, CIRM has been committed to a multifaceted approach that includes a focus on both rare and prevalent diseases. Key areas of emphasis include:

- **Development of Cell and Gene Therapies:** CIRM is currently committed to advancing of cell and/or gene therapies from research to market, through CIRM's clinical trial funding model and clinical infrastructure, emphasizing not only patient access but also the scaling of manufacturing processes to meet clinical demand.
- **Collaborative Networks for Discovery Research:** CIRM is fostering collaborative networks to unite multidisciplinary teams, enhancing our understanding of disease mechanisms and leading to the discovery of novel targets and biomarkers that will push the boundaries in treatment development for these diseases. In line with Proposition 14's emphasis, CIRM has prioritized the development of treatments for neurological conditions.
- **Training and Workforce Development:** CIRM's educational initiatives have set a new standard for workforce development in regenerative medicine, creating a comprehensive network that connects training with real-world application.
- **Advancements in Regenerative Medicine Technologies:** By supporting initiatives which advance our understanding of complex diseases, CIRM hopes to translate scientific excellence



into substantial patient benefits. CIRM has supported research to improve the development of technologies such as cell reprogramming, gene editing, therapy delivery systems, and others, ensuring the continuous evolution of the field.

4 – STRATEGIC ALLOCATION FRAMEWORK

In the context of CIRM’s strategic planning, the framework being established will outline objectives, scope, pertinent questions, data requirements, timeline, and stakeholder roles to guide the organization’s strategic allocation and prioritization decisions. Under this framework, a data-driven funding strategy will enable CIRM to reassess funding allocations, *focusing on impact potential, patient reach, technological feasibility, and prospects of regulatory approval*. Additionally, provisions will be made for emerging opportunities and unforeseen challenges.

| FRAMEWORK | |
|----------------------------|---|
| Design Questions | <ol style="list-style-type: none"> 1. How can CIRM make the greatest impact on its mission? 2. How might CIRM effectively allocate its remaining budget of \$3.54B to balance the urgent need for advancing regenerative medicine research and achieving significant milestones, while also ensuring sustainable investment in workforce development and infrastructure, in alignment with its mission? |
| Considerations | <p>Across all areas of CIRM funding, the team will underscore the importance of strategic alignment with long-term objectives, efficient resource allocation, and the impact on patient care and scientific advancement. The considerations reflect a holistic approach to addressing both the current and future needs of the field, prioritizing both innovation and sustainability.</p> <p>The goal is to guide decision-making by highlighting key areas of focus, potential challenges, and opportunities for enhancing the impact of CIRM’s investments in regenerative medicine. The team will underscore the importance of strategically aligning CIRM’s funding programs, grantmaking processes and overall resource allocation with the intent of Proposition 14, which is to support stem cell research to mitigate or cure chronic diseases and injury and thereby reduce or mitigate human suffering and the cost of care and improve the health and productivity of Californians. The considerations reflect a holistic approach to addressing both the current and future needs of the regenerative medicine field in order to deliver on its potential for transforming the lives of patients, as intended by Proposition 14.</p> |
| Data & Analysis | In the process of strategic allocation and prioritization, various data sets and information categories will be compiled and analyzed, each playing a crucial role in informing decisions. |
| Recommendations | The leadership team at CIRM is set to consolidate data and analysis by September to deliver a comprehensive set of recommendations. |

5 – NEXT STEPS

1. Collect data & analyze.
2. Provide recommendations.

6 – TIMELINE

