CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Strategic Allocation Framework

FREQUENTLY ASKED QUESTIONS

What is the Strategic Allocation Framework (SAF)?

- The Strategic Allocation Framework (SAF) is a data-driven approach designed to prioritize resource allocation to maximize the Agency's impact. Through the SAF, CIRM will reassess funding allocations, placing emphasis on projects with high-impact potential, broad patient reach, technological feasibility, and strong prospects for regulatory approval.

When did the SAF effort begin?

- The SAF effort began in September 2023, when the Science Subcommittee requested CIRM leadership to develop a structured approach for resource allocation. Final recommendations were presented and approved in September 2024.

Why did CIRM develop the SAF?

- CIRM developed the SAF to address the increasing demand for funding in the rapidly evolving field of regenerative medicine. The SAF ensures that CIRM's remaining resources are used strategically to meet the current and future challenges in developing transformative therapies.

How does the SAF impact CIRM's research priorities?

- Through the SAF approach, CIRM will focus on high-potential research projects, particularly those addressing unmet medical needs or diseases that have been historically underfunded. This approach aims to accelerate the translation of research into clinical applications, ensuring that patients benefit from innovations more quickly.

What are the remaining funds at CIRM?

- CIRM has a remaining balance of $3.86 billion.

What guiding questions were used to inform the SAF?

- The guiding questions for the SAF include:

    1. How can CIRM make the greatest impact on its mission?

    2. How might CIRM effectively allocate its remaining budget of $3.86B?

    3. Within these, how might CIRM effectively allocate its remaining Neuro budget of $1.14B?

How is the SAF a data-driven project?

- The SAF is informed by extensive internal and external key datasets, including public health data, portfolio analyses, clinical research outcomes, economic impact assessments, industry analyses, and insights from both scientific literature and subject matter experts. This involved gathering relevant information and metrics needed to assess progress and impact. The CIRM team conducted thorough analyses of these datasets to draw insights and develop a well-rounded understanding of the potential outcomes of each SAF recommendation.

Is CIRM creating a new strategic plan?

- The SAF provides more granularity and builds on CIRM's established strategic plan, mission, and goals from 2022, focusing on more targeted, data-driven allocation of resources.

What are the key impact goals of the SAF?

- The SAF has six key goals across four categories: accelerating discovery and translation, advancing cell and gene therapy approvals, improving accessibility and affordability, and bolstering workforce development. Each goal is designed to maximize CIRM's impact in the regenerative medicine field.

What role does accessibility play in the SAF?

- Accessibility is a key component of the SAF. CIRM is committed to making innovative treatments available to all patients, especially those in underserved communities. The SAF supports initiatives that reduce the cost of therapies and improve healthcare infrastructure, ensuring broader access to life-saving treatments.

How will the SAF benefit people throughout California?

- CIRM's SAF approach directly benefits patients by prioritizing high-impact research, ensuring that innovative treatments are accessible to all. Key recommendations focus on accelerating the development of new therapies, reducing treatment costs, and training a workforce to meet the demands of the growing regenerative medicine field.

How do the new priorities differ from what has happened over the last 20 years?

Over the last 20 years, CIRM has contributed greatly to regenerative medicine through broad funding initiatives. With the Strategic Allocation Framework (SAF) under Proposition 14. The new priorities differ in key ways:

- **Focused Resource Allocation**: We're shifting from broad-based funding to targeted investments in high-potential areas, ensuring resources are allocated for maximum impact on clinical and patient outcomes for both rare and prevalent disease in CA.

- **Discovery and Translational Research**: There's a strong emphasis on accelerating the identification of novel biomarkers and therapeutic targets, while developing technologies to improve the safety, efficacy, and quality of therapies. Through a collaborative multidisciplinary approach CIRM aims to bridge gaps that have traditionally slowed the translation of basic science into clinical practice**.**

- **Advancing Therapies to FDA Approval**: Earlier, CIRM emphasized expanding the number of clinical trials. Now, the focus is on moving therapies through clinical trials toward FDA approval with clear success metrics. This includes balancing translational and basic research to ensure a continuous pipeline of innovation.

- **Targeted Rare Disease Initiatives:** The SAF places special emphasis on pushing rare disease therapies toward Biologics License Application (BLA) readiness, accelerating their advancement through late-stage trials, and addressing gaps in areas that have been historically underfunded.

- **Improving Access and Affordability**: While we don't have direct control over pricing and reimbursement, we are committed to educating both public and private payors on the long-term economic benefits of one-time cell and gene therapies versus lifelong treatment costs. Our goal is to ensure that innovative therapies reach patients and demonstrate their value to the healthcare system. CIRM is focused on making cell and gene therapies more accessible by addressing financial barriers and ensuring treatments reach a broader range of patients. Through strategic partnerships and initiatives, we are working to enhance access to specialized treatment centers. These efforts align with our broader goals of accelerating therapy development and improving patient outcomes.

- **Diverse Workforce Development:** Recognizing the need for a skilled workforce to support the future of regenerative medicine, CIRM is expanding programs like Bridges and COMPASS to develop a more diverse and hybrid-skilled workforce capable of sustaining the momentum of innovation in this field.