



MEMORANDUM

TO: Vice-Chair Bonneville and Members of the AAWG
FROM: Rosa Canet-Avilés, Vice President, Scientific Programs & Education
SUBJECT: Strategic Allocation Framework Updates and AAWG role
DATE: MAY 14TH 2024

Dear Members of the AAWG,

We are reaching out to request your valuable feedback on Goal #2 of the Strategic Allocation Framework (SAF) which outlines our proposed strategy for prioritizing resource allocation within the CIRM. Attached you will find a set of slides prepared for the upcoming AAWG meeting scheduled for May 14, 2024.

Summary of the Strategic Allocation Framework: The SAF has been developed to guide the California Institute for Regenerative Medicine (CIRM) in strategically allocating CIRM's funding across a spectrum of initiatives, aiming to optimize impact within the field of regenerative medicine. Key components of the framework include:

1. **Background and Rationale:** As CIRM has finite resources and a broad mandate, the need for a strategic approach to allocation is critical. This approach is centered on balancing the drive for innovation with the imperative for treatments to be both accessible and affordable.
2. **Strategic Allocation Process:** The framework is structured to reassess funding allocations by focusing on impact potential, patient reach, technological feasibility, and regulatory prospects.
3. **Impact Goals and Categories:** This process begins with defining our SAF Categories. These will ultimately lead to the Impact Goals with measurable success metrics. These goals articulate the desired outcomes and milestones we aim to achieve, ensuring that every dollar allocated moves us closer to our vision. For the purposes of our upcoming discussion, we are focusing on Goal 2 (slide #14) corresponding to Category #2.

Overview of the Slides for AAWG Meeting

The slides to be presented aim to:

- Provide a background on the evolution of the regenerative medicine landscape and its implications for CIRM's strategic planning.
- Detail the process and methodology of the SAF, emphasizing the data-driven approach to decision making.
- Discuss strategic priorities, with a focus on specific impact goal #2 and success measures.
- Outline the timeline for implementation and feedback phases.

Feedback on Goal #2:

We specifically seek your insights on Goal #2, which aims to ensure every CIRM-funded project that completes an advanced clinical trial has a strategy to enable access and affordability (A/A) for all Californians, particularly underserved populations. Your feedback with regards to the goal and the questions that we have designed to evaluate its feasibility and recommend implementation steps will be instrumental in refining our strategies and ensuring that they align with both CIRM's long-term objectives and immediate needs.

Goal #2: Ensure that every CIRM funded project completing advanced clinical trial has a strategy that enables access and affordability by all California patients, particularly underserved populations.

- **Assessment of Current Landscape:** What is the current landscape for public and private payer coverage access and affordability within cell and gene therapies (CGTs)?
- **Impact Factors:** What are the most significant factors that influence the success of access and affordability initiatives?
- **Barriers:** What are the main obstacles, including knowledge gaps, that could hinder the implementation of effective A/A strategies?
- **Alignment with Regulatory / Reimbursement Models:** How can CIRM align with the CMS CGT access model to enhance the impact of our programs?
- **Data Utilization:** How can we leverage data from non-CIRM-funded programs to inform our strategies? Are there specific areas where CIRM needs to acquire more data to formulate effective A/A strategies?

- **Implementation:** What are the best practices for implementing A/A strategies across various projects? How can the AAWG's funding mechanism support these efforts?
- **Policy Development:** What general policies or resources could CIRM develop to facilitate A/A, and how should they be integrated within each project's strategy?
- **Scaling Strategies:** At what stage should project applicants provide their A/A plans, and how can these strategies be effectively scaled?

Preparation for Discussion: Please review the above questions and attached slides and come prepared to discuss the questions that will inform CIRM's recommendations and help shape our strategic priorities moving forward.

We value your contributions to shaping the future of regenerative medicine funding in California and look forward to a productive discussion.

Thank you for your attention and collaboration.