CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Memorandum

To: Members of the Science Subcommittee
From: CIRM EDEV Programs Leads
Re: EDEV concept
Date: November 23, 2026

Executive Summary

CIRM proposes to launch the EDEV or "Early Development" Awards, a new funding opportunity to accelerate progression of stem cell-based and genetic therapy candidates and ready them for transition to preclinical development.

	DISC2	EDEV	Rationale
Scope	Therapeutics, biomarkers, devices, diagnostics, tools	Therapeutics only	SAF priorities, CIRM runway
Outcome	Single candidate	Single candidate	No change
Duration	1, 2, or 3 years to deliverable	2 years to deliverable	Focus on critical path; projects best suited for value planning
Critical Roles	Principal Investigator	Principal Investigator Project Manager	Support and maintain focus on critical path
Value Add	Proactive award management	Proactive award management with product value planning	Improved derisking for future investment; increased probability of success

Table 1. EDEV builds on DISC2 program, updates and aligns with SAF.

EDEV will serve as a bridge between the discovery of validated disease targets and preclinical/clinical development, addressing a stage of research that was previously supported through CIRM's DISC2 Quest Awards (2016–2025). This stage is essential for developing the evidence base and exploring the value drivers needed to secure further investments for advancing promising new candidates from the bench to the bedside.

While conceptually similar to DISC2, EDEV incorporates several improvements and innovations to better align with CIRM's Strategic Allocation Framework (SAF), directly impacting goals related to discovery and translation of new therapeutics (Improvements Summarized in Table 1)

The maximum EDEV Award will be $1,850,000, inclusive of direct and indirect costs, with $50,000 earmarked for expert advising on product value planning. We propose a maximum Award duration of two years, and we anticipate the program will recur annually (Table 2).

	EDEV
Recurrence	Annual, starting FY 27/28
Max Duration	Up to 2 years
Award Amount	Up to $1.85M in total costs
Award Structure	Project Milestones
Awards/Year	13-16
Total Funds/Year	$25M

Table 2. EDEV: Summary of Proposed Features.

The remainder of this memo outlines the EDEV concept in more detail, followed by a request for the Science Subcommittee to provide feedback and recommend the concept to the ICOC for approval.

I. Background

In September 2024, CIRM's Governing Board approved a Strategic Allocation Framework (SAF) to guide its investments, setting ambitious goals to accelerate the development and translation of innovative therapies including Goal 1 (validating at least four novel disease targets/biomarkers) and Goal 4 (advancing therapies into late-stage clinical trials). To achieve these goals, CIRM envisioned a series of programs forming a sustained funding pipeline that supports and derisks each stage of research and development, from target identification through biologics license application. CIRM moved quickly to implement this pipeline, launching DISC4 and DISC5 to identify and validate novel disease targets and biomarkers in direct support of Goal 1, and introducing PDEV (Preclinical Development) to advance nominated therapeutic candidates toward IND-enabling studies in support of Goal 4.

CIRM is now launching EDEV to identify and confirm promising candidates and generate evidence of disease-modifying activity, bridging discovery and preclinical development across the "valley of death" and linking Goals 1 and 4. EDEV builds on the decade-long success of CIRM's DISC2 Quest Awards (2016–2025), where nearly 40%

of programs successfully identified candidates with disease modifying activity in the active award period. The EDEV mechanism has been optimized to align with SAF goals, adapt to the present regulatory and economic landscape, and better derisk candidates for PDEV or external investment through the introduction of product value driver planning. The addition of EDEV to CIRM's pipeline of R&D programs will help ensure CIRM meets its goals by maximizing the likelihood that promising new discoveries progress into clinical trials.

II. Proposal

Scope

EDEV will support critical path activities necessary to identify a lead candidate or confirm an existing one, demonstrate reproducible disease-modifying activity, and develop a progression plan, including refined product value drivers, that positions the candidate to enter preclinical development. EDEV will not support preclinical/clinical development activities, which are targeted by CIRM's later-stage PDEV, RAPID, and CLIN2 programs. EDEV will also not support exploratory research to identify new disease or new therapeutic targets, which are prioritized by CIRM's DISC4 and DISC5 programs.

Objective and Expected Outcome

The Objective of the EDEV program is to accelerate the progression of stem cell-based and genetic therapy candidates and ready them for transition into preclinical development.

Accordingly, the expected outcome of an individual EDEV Award (or deliverable), is a translatable, lead therapeutic candidate with reproducible disease-modifying activity and a progression plan that includes refined product value drivers.

Key Components

EDEV Guiding Principles

Guiding principles are how CIRM translates the SAF recommendations into portfolio outcomes. Guiding principles shape program objectives, inform the criteria by which projects are selected for merit review and scientifically evaluated, and inform the recommendations that CIRM teams bring to the Application Review Subcommittee (ARS) to support funding decisions.

The EDEV program aims to build a portfolio of Awards that are responsive to an evolving research landscape and have the potential to strengthen the preclinical

development pipeline by advancing innovative stem cell and genetic therapies with the potential for transformative impact. To achieve this objective, the EDEV portfolio will prioritize programs that:

- Have potential to deliver transformative improvements in patient outcomes, through candidates that are differentiated from existing approaches and have a credible development path
- Anticipate barriers to patient access to stem cell-based and genetic therapies and account for them early in product design
- Broadly address both prevalent and rare diseases affecting Californians

Project Eligibility

To ensure proposals are sufficiently developed to achieve the expected outcome in the allowed project duration, EDEV will require applicants to meet defined entry criteria to be eligible and competitive for funding. Importantly, applicants must propose the necessary (i.e. critical path) activities that are required to position a therapeutic candidate for progression to the stage of preclinical development that is targeted by CIRM's PDEV and RAPID programs. In addition, the applicant must provide evidence that the proposed therapeutic target is associated with a relevant human disease or biological process. These criteria favor projects with the greatest likelihood of impacting CIRM's SAF goals 1 and 4 and best suited to benefit from proactive award management and expert consultation for value planning that will accompany this new program.

Budget Framework

The CIRM Team has long-term experience administering grants that support candidate discovery, most recently through the DISC2 Quest Awards (2016-2025), and earlier through the Early Translation program (2008-2012). Based on actual expenditures and timelines for a broad array of candidate types, we are proposing a streamlined, two-year grant mechanism with a budget capped at $1,850,000 for EDEV, inclusive of direct and indirect costs. Of this amount, $50K will be earmarked to support specialized expert consulting (product value planning for progression, see below) This budget takes into consideration the current economic landscape, industry feedback, and an analysis of success rates for previous iterations of DISC2 that varied by level of support and duration. These factors suggest a two-year award duration provides CIRM the best opportunity to impact SAF goals given the current funding landscape, the remaining CIRM runway, the anticipated annual allocation of $25M, and the bolus of CA-based programs that are scientifically poised to move rapidly to preclinical development with support of this new program.

Product Value Planning

A therapy's value is shaped by a set of drivers: the size and identifiability of the patient population, annual incidence, the standard of care and the associated unmet need, the competitive landscape, pricing and reimbursement, market uptake, manufacturing scale and cost, intellectual property (IP), and regulatory strategy. These drivers determine whether a program can attract the follow-on investment needed to reach patients. Several of these factors are largely fixed once a candidate is chosen, so planning that begins only at IND-enabling or clinical stages comes too late to meaningfully shape them.

CIRM's PDEV, RAPID, and CLIN2 programs already address these elements through their Value Proposition, Patient Access, and Market Access and Commercialization planning requirements. We propose extending these existing requirements back into EDEV in a stage-appropriate way. At entry, awardees would describe the intended patient population, annual incidence, standard of care, and competitive landscape (Figure 1). By exit, they would refine those elements and add manufacturing, IP, and regulatory strategy.

CIRM will provide $50K at the start of an a EDEV award for consultant support. This allows awardees flexible use of these funds as they gradually develop the updated product value drivers expected by EDEV exit. This stage-appropriate approach to product value planning better positions any identified therapeutic candidate for a stronger PDEV or RAPID application and for sustained investment through later stages of development.

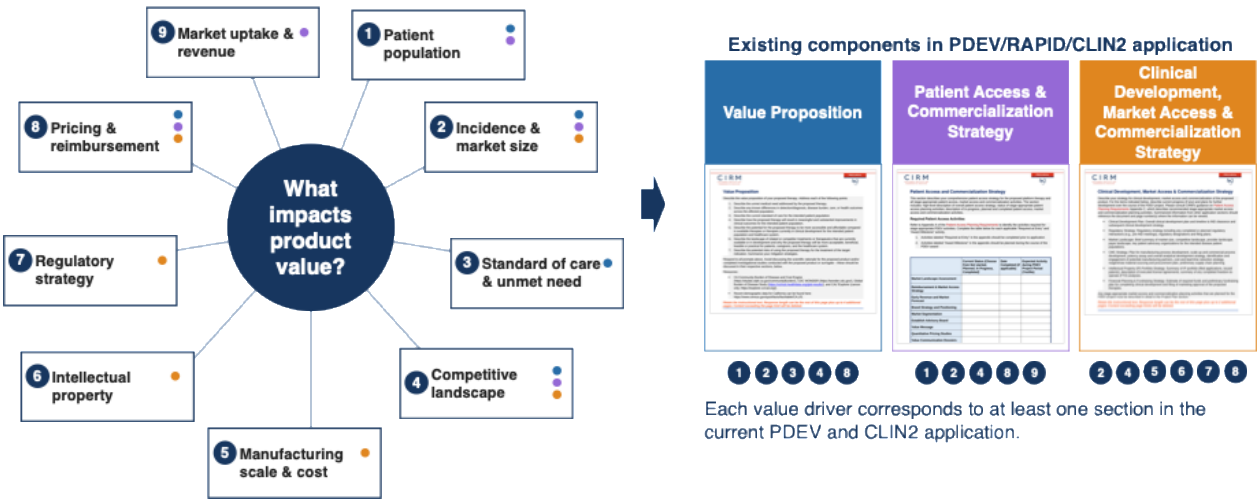


Figure 1. Early Planning of Product Value Drives Later Investment. Description of Value Drivers and the relevant application components from CIRM's later stage programs.

Delivery Model

The EDEV funding opportunity will be offered once a year through a posted Program Announcement. CIRM anticipates requesting an annual budget of $25M to support approximately 13-16 new EDEV Awards each year.

Application and Review

CIRM anticipates high volumes of EDEV applications. In alignment with other new CIRM programs, EDEV will utilize:

- A two-step review process. The first step, GWG selection, enables selection of the subset of applications that are most responsive to the funding opportunity and hold the greatest potential for impact. The second step is a full GWG review of the selected applications
- A 1-100 numerical scoring system to provide granularity into score driving decisions

III. Timeline and Next Steps

Following our meeting with the Science Subcommittee on November 23, 2026, the team will finalize the EDEV concept for ICOC presentation and approval on December 10, 2026.

IV. Summary of Requested Action

CIRM requests Science Subcommittee feedback and recommendation of the EDEV concept to the ICOC for approval.