EDEV Awards: Funding Opportunity for Early Development Stage Research

Summary

OVERVIEW	
Objective	To accelerate the progression of stem cell-based and genetic therapy candidates and ready them for transition to preclinical development
Scope	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
Program Recurrence	Once per year

AWARD DETAILS	
Maximum Award Amount	$1,850,000
Maximum Award Duration	2 years

ELIGIBILITY REQUIREMENTS	
Applicant	Must meet CIRM's definition of a California Organization
Critical Roles	The Principal Investigator (PI) must commit at least 20% effort. The project team must include an experienced Project Manager who commits at least 25% effort.
Key Personnel with Required Expertise	The project team must include an experienced data project manager

SCHEDULES AND DEADLINES	
GWG Selection	Approximately 60 days post submission deadline
GWG Review	Approximately 60 days post GWG Selection
Award Approval	Next available Application Review Subcommittee meeting
Start Date	Must be ready to start Award activities within 90 days of Award approval

CONTACT AND ADDITIONAL RESOURCES

https://www.cirm.ca.gov/researchers/funding-opportunities-discovery-stage-research/

For additional information on the program or Applications, contact discovery@cirm.ca.gov. For questions related to the review and approval of Applications, contact review@cirm.ca.gov. For additional information or questions on budgets or allowable costs, contact grantsmanagement@cirm.ca.gov.

Additional requirements and definitions may be found in **CIRM's Award Management Policy** and **CIRM Funding Opportunities: Common Requirements and Definitions**, and are incorporated herein by reference.

Background

The mission of the California Institute for Regenerative Medicine (CIRM) is to accelerate world class science to deliver transformative regenerative medicine treatments in an equitable manner to a diverse California and world.

In September 2024, CIRM's Governing Board, the Independent Citizens' Oversight Committee (ICOC), approved a Strategic Allocation Framework (SAF) to guide and optimize the value of CIRM's

current and future investments. The SAF set ambitious goals to accelerate the development and translation of innovative therapies, including Goal 1: catalyzing the identification and validation of at least four novel targets or biomarkers and integrating them into preclinical or clinical research for diseases affecting Californians; and Goal 4: accelerating the progression of therapies for these diseases 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 accelerate the progression of stem cell-based and genetic therapy candidates to readiness for preclinical development. Starting from targets with supporting human evidence, EDEV teams will identify a lead candidate or confirm an existing one; and build a robust body of evidence for disease modifying activity. Teams will also develop a progression plan that refines the candidate's product value drivers, the features that the product must deliver to reach and benefit patients, which will guide decisions as it moves further into development. EDEV bridges discovery and preclinical development by supporting the critical activities needed to carry candidates through the "valley of death", thereby linking Goals 1 and 4. It builds on nearly a decade of success from CIRM's DISC2 Quest Awards (2016–2025), which seeded California's regenerative medicine community with promising therapeutic candidates and approaches, while evolving the model to align outcomes with the SAF goals, respond to today's regulatory and economic landscape, and further derisk candidates for progression into CIRM's PDEV program or for external investment.

Objective

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.

Program 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

Scope and Structure

The EDEV program supports activities required to achieve the **expected outcome:**

A translatable lead therapeutic candidate with reproducible disease-modifying activity, and a progression plan that includes refined product value drivers.

EDEV awards will support research activities to select a new lead candidate or build on an already existing one. Within the two-year award period, the team must demonstrate reproducible disease modifying activity with their lead candidate and produce a progression plan that positions the candidate to enter preclinical development, through CIRM's PDEV program or external investment.

Research teams must conduct activities associated with managing, preserving, and sharing data and knowledge from the study to benefit the broader scientific community.

The scope of an EDEV award also includes support for the following activities:

✓	Preparation for and conduct of stage-appropriate regulatory meetings (e.g., INTERACT)
✓	Engagement activities with trainees supported through CIRM's EDUC or INFR programs
✓	Developing assays, including New Approach Methodologies (NAMs) and AI platforms, in support of meeting expected outcome
✓	Outreach to patient communities or partnering with patient centered organizations; communication of research to the wider public

Allowable Use of CIRM Funds

Applicants may request funds to cover costs for research activities conducted wholly in California and may also request costs for activities conducted outside of California, provided that the California Organization exercises direction and control over the activities.

CIRM funds must be used to carry out proposed research activities directly related to achieving the expected outcome and in-scope activities described above including the costs of personnel, trainees, supplies, travel, equipment, and subcontracts, consistent with CIRM's Award Management Policy (AMP). This includes the $50,000 earmarked for expert advising on product value planning.

CIRM funds **cannot** be used to support the following activities under this opportunity:

UNALLOWABLE ACTIVITIES	
✘	Preclinical and clinical development activities that are targeted by CIRM's later stage programs including PDEV, RAPID, CLIN2
✘	Exploratory research to identify new therapeutic or disease targets
✘	Activities already budgeted or paid for under a prior, existing or pending CIRM Award, or which are already supported by another funder
✘	The costs of activities performed by a separate out-of-state organization that retains intellectual property or independent publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM-Funded Project
✘	Costs incurred on or before the date of ICOC approval

Award amount and duration

The maximum amount of funding that may be requested for an EDEV Award is $1,850,000 per Award, inclusive of direct project costs and Indirect Costs. Of this total, $50,000 will be earmarked to support expert advising for product value planning, subject to adjustment based on changing needs. The maximum Award duration is two (2) years.

The amount requested must be adequately justified. The requested amount is subject to adjustments prior to the issuance of an Award based on assessments by the Grants Working Group (GWG), the CIRM team, or by the Application Review Subcommittee of the ICOC. CIRM funds will be disbursed to the Applicant, which will be responsible for subsequent disbursement of funds (Subawards/Subcontracts) to Co-Investigators and Key Personnel.

Award management

All Awards made under this opportunity are subject to CIRM's standard Award terms, including requirements related to intellectual property, data sharing, reporting, and Award administration. These terms are set forth in CIRM's applicable regulations; including, but not limited to, the CIRM Award Management Policy.

GWG Application selection

If the number of Applications submitted exceeds the volume that can reasonably be reviewed by the GWG panel, the GWG will conduct an initial screening to identify those Applications that best align with the EDEV program objectives. The basis for selection will be defined in the EDEV Program Announcement. Applications receiving the highest overall reviewer assessments, consistent with the target number established for GWG Merit Review, will advance to full panel discussion. The CIRM President and CEO, upon recommendation from CIRM scientific staff, may advance a limited number of additional Applications not selected by the GWG if there is a compelling programmatic justification. Reviewers may provide brief comments or categorical assessments at this stage; however, detailed feedback to Applicants is not guaranteed.

Provisional timetable

The EDEV funding opportunity will recur annually. The timeline of each funding cycle is as follows:

PROVISIONAL TIMETABLE	
GWG Selection	Approximately 60 days after Applications due
GWG Discussion	Approximately 120 days after Applications due
Application Review Subcommittee Award Approval	Next available Application Review Subcommittee meeting
Award Start	Approximately 90 days after Award approval

Eligibility

All the following requirements must be fully satisfied for an Application to be accepted and considered for funding by CIRM. Please reference CIRM's **Award Management Policy**, **CIRM Funding Opportunities: Common Requirements and Definitions**, and CIRM's **Manage Your Award** page for additional requirements for CIRM Awards.

ELIGIBILITY REQUIREMENTS	
1	The proposed project must be in scope and designed to culminate in the expected outcome.
2	The Application must demonstrate readiness by meeting the below criteria: • Human genetic, cellular or patient-derived data support the relevance of the therapeutic target to the disease; AND • Modulating the target affects a disease-relevant cellular or biological process in an experimental model For cell replacement approaches, the target is the cell type or function that the product is intended to restore.
3	The project team must include a Project Manager with demonstrated project management experience who commits at least 25% effort.
4	The project team must include personnel dedicated to data project management.
5	The PI must not currently have another Application that is substantially similar or has overlapping activities pending review or approval under any CIRM funding opportunity.
6	The PI must commit a minimum of 20% effort and adhere to CIRM's requirements.
7	The Applicant must be ready to initiate work on the funded project within 90 days of Award approval.
8	The Application must be accurate and complete.
9	The Applicant must meet CIRM's definition of a California Organization.
10	For-Profit Organizations must demonstrate solvency.
11	The Applicant must meet CIRM's requirements for Good Standing.