PDEV (Preclinical Development Awards: Funding Opportunity for Preclinical Stage Projects)

Summary

OVERVIEW			
Objective		To accelerate completion of preclinical development, FDA IND clearance, and clinical trial startup for stem cell-based and genetic therapies	
Scope		CIRM will support activities in the Pre-IND stage and/or the IND-enabling stage	
Program Recurrence		Twice per year	
AWARD DETAILS			
Maximum Award Amount		Up to $13,000,000 total cost	
Maximum Award Duration		Up to 5 years (60 months)	
Stage-specific Amount and Duration	**Stage**	**Early PDEV (Pre-IND)**	**Late PDEV (IND-Enabling)**
	Amount	$5,500,000	$7,500,000
	Duration	30 months (inclusive of maximum optional 6 months for candidate optimization)	30 months (inclusive of maximum optional 6 months for trial startup activity following IND clearance)
ELIGIBILITY REQUIREMENTS			
Applicant Organization		Only non-profit or for-profit organizations that meet CIRM's definition of a California Organization are eligible to apply	
Applicant PI		The PI must commit a minimum of 15% effort	
Project Manager		The project team must include an experienced project manager at a minimum 50% effort	
Co-funding		**Unpartnered Non-Profit**: None Required; **Non-Profit with For-Profit Partner**: 20% of allowable project costs; **For-Profit**: 20% of allowable project costs The minimum co-funding requirement may be fulfilled by cash-based or warrant-based co-funding	
Stage Readiness		The application must provide data demonstrating that reproducible disease-modifying activity was achieved with the proposed candidate	
SCHEDULES AND DEADLINES			
Pre-submission Due Date		Twice per year	
Application Due Date		Twice per year, approximately 60 days after pre-submission deadline	
GWG Review		Approximately 60 days after application submission deadline	
Award Approval		Approximately 120 days after application submission deadline	
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-translational-research/

For additional information on the program or applications, contact preclinical@cirm.ca.gov. For questions related to the review and approval of applications, contact review@cirm.ca.gov.

Additional requirements and definitions may be found in **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 of 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. One key outcome of this exercise was defining an ambitious goal for CIRM, through its preclinical and clinical stage opportunities, to propel 15-20 therapies targeting diseases affecting Californians to late-stage trials.

The Preclinical Development (PDEV) program is a part of CIRM's core product development programs that, unlike other funding sources, provide reliable and predictable funding throughout the award period, and bring expert CIRM staff and advice to support accelerated outcomes and advancement of projects along key stages of the product development pathway.

Through the PDEV Program, CIRM will support and accelerate preclinical development of transformative stem cell-based and genetic therapies that otherwise are not adequately supported by federal funding and are too risky for substantial private investment. The PDEV program will advance a pipeline of innovative therapies for diseases affecting Californians to first-in-human clinical trials and will contribute toward the CIRM impact goal of advancing 15-20 therapies to late-stage clinical trials. Under this funding opportunity, CIRM will support preclinical development of stem cell-based and genetic therapeutic approaches that not only offer potential for transformative clinical impact but also meaningfully address current barriers to patient access and affordability.

Objective

The objective of this program announcement is to accelerate completion of preclinical development, FDA IND clearance, and clinical trial startup for stem cell-based and genetic therapies.

Under the PDEV program, CIRM will act not only as a funding agency, but will also devote significant internal resources and leverage its external team of world-class subject matter experts to actively advance the project. The result of a successful application will be the formation of a true partnership that both accelerates the program and gives it the greatest opportunity for success.

This vision is achieved through critical path funding opportunities supporting research at different stages of maturity, with an emphasis on data and knowledge sharing, open innovation, and leveraging synergies across CIRM-funded programs, to propel therapeutic candidates to first-in-human clinical trials.

Scope and Structure

CIRM will enable completion of all necessary preclinical development stage activities and achievement of IND clearance of a stem cell-based or genetic therapy candidate for eventual conduct of a first-in-human clinical trial. The expected outcome of all PDEV awards is the clearance of an IND application with the FDA for the stem cell-based or genetic therapy candidate.

Applicants may propose preclinical development activities ranging from candidate optimization to IND submission and trial startup. For purposes of the CIRM grant application and award contracting, the allowable project activities are divided into two stages: Early PDEV (pre-IND) and Late PDEV (IND-enabling).

Conduct of CIRM-funded pre-IND meeting, IND-enabling studies and GMP manufacturing activities in any given PDEV award will be subject to CIRM prior review with the exception of projects that have already conducted a pre-IND meeting for the proposed therapeutic candidate in the proposed disease indication prior to application submission.

Program funding areas

The PDEV program aims to enrich the clinical pipeline with innovative stem cell-based and genetic therapies that have the potential for transformative clinical impact and which address barriers to patient access and affordability.

To support this goal, certain modalities, disease areas, and project features will be given preference based on their potential to achieve these goals. These preferences will be informed by funding opportunity performance, award portfolios, the evolving regenerative medicine scientific and regulatory landscape, and other strategic considerations. Each year, CIRM staff will present preference recommendations to the ICOC, which retains sole authority for approval. Once approved, these preferences will be implemented through the PDEV pre-

submission process (described below) and during programmatic considerations by the Application Review Subcommittee of the ICOC.

Program activities

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

CIRM **will fund** the following activities under this opportunity:

ALLOWABLE ACTIVITIES: EARLY PDEV (PRE-IND) STAGE	
✓	All activities necessary to ready a human therapeutic candidate for pivotal IND-enabling preclinical studies including preparation and conduct of a pre-IND meeting with the FDA
✓	All activities necessary to optimize a candidate and to confirm disease-modifying activity for the finalized single human therapeutic candidate
ALLOWABLE ACTIVITIES: LATE PDEV (IND-ENABLING) STAGE	
✓	All IND-enabling activities necessary for submission and clearance of an IND with the FDA for a clinical trial with the therapeutic candidate
✓	Clinical trial startup activities to facilitate eventual rapid recruitment of patients
ALLOWABLE ACTIVITIES: ACROSS ALL STAGES	
✓	Activities associated with managing, preserving, and sharing data and knowledge from the project

CIRM **will not fund** the following activities under this opportunity:

UNALLOWABLE ACTIVITIES ACROSS ALL STAGES	
✗	The conduct of a clinical trial beyond start-up activities
✗	Patient recruitment, screening, or enrollment
✗	Activities already budgeted or paid for under a prior, existing or future CIRM award
✗	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
✗	Project costs incurred on or before the date the Application Review Subcommittee of the ICOC approves the application for funding

Award amount and duration

CIRM expects projects to rapidly advance through stages of pre-clinical development to IND clearance and will not accept applications under this program that propose project timelines in excess of limits described below.

Applicants may request CIRM support for pre-clinical development activities spanning pre-IND and IND-enabling stages. The maximum overall award amount and duration as well as maximum funds requested and duration for each individual stage are described below.

MAXIMUM AWARD AMOUNT	MAXIMUM AWARD DURATION

$13,000,000	5 years (60 months)

STAGE	MAX STAGE AMOUNT	MAX STAGE DURATION
Early PDEV (Pre-IND)	$5,500,000	30 months (inclusive of maximum optional 6 months for candidate optimization)
Late PDEV (IND-enabling)	$7,500,000	30 months (inclusive of maximum optional 6 months for trial startup activity following IND clearance)

The amount of total project costs requested must be adequately justified and is subject to adjustments prior to issuance of an award based upon assessments of the Grants Working Group (GWG), the CIRM team, or by the Application Review Subcommittee of CIRM's Governing Board.

Pre-submission process

All prospective applicants to the Preclinical Development Funding Opportunity will be required to submit a brief pre-submission form prior to the pre-submission deadline. The objective of the pre-submission process is to invite a set number of applications that are responsive to the Preclinical Development program funding areas and that are reviewable by the Grants Working Group in a single submission cycle. Selected pre-submissions will be invited to submit a complete application for the upcoming application submission cycle.

Provisional timetable

The PDEV funding opportunity will recur twice per year. The anticipated timeline of each funding cycle is as follows:

PROVISIONAL TIMETABLE	
Pre-submission open	Twice per year, approximately spring and fall
Pre-submissions due	Approximately 30 days after pre-submissions open
Applications open for invited projects	Approximately 30 days after pre-submission deadline
Applications due	Approximately 30 days after applications open
Grants Working Group (GWG) review	Approximately 60 days after application due date
Application Review Subcommittee award approval	Approximately 60 days after GWG review
Award start	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. Requirements marked with a * [or similar]: incorporate by reference the requirements and definitions described in **CIRM Funding Opportunities: Common Requirements and Definitions.**

ELIGIBILITY REQUIREMENTS	
1	The application must propose studies to support the filing of a single IND for a regenerative medicine-based therapeutic (stem cell-based or genetic therapy*)

2	The application must provide data demonstrating that reproducible disease-modifying activity was achieved with the proposed candidate
3	The PI must commit a minimum of 15% effort and adhere to CIRM's requirements*
4	The project team must include an experienced project manager at a minimum 50% effort
5	The project team must include data management experience
6	The applicant must be ready to initiate work on the funded project within 90 days of approval
7	The application must be accurate and complete
8	The applicant organization must meet CIRM's definition of a California Organization*
9	The applicant must propose appropriate co-funding* and demonstrate availability of funds (required minimum 20% of total allowable costs for non-profit with for profit partner or for-profit applicant)
10	For-profit organizations must demonstrate solvency*
11	The applicant must meet CIRM's requirements for "good standing"*