



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

## Summary

OVERVIEW			
<b>Objective</b>	To accelerate completion of preclinical development, FDA IND clearance, and clinical trial startup for stem cell-based and genetic therapies		
<b>Scope</b>	CIRM will support activities in the Pre-IND stage and/or the IND-enabling stage		
<b>Program Recurrence</b>	Once per year		
AWARD DETAILS			
<b>Maximum Award Amount</b>	Up to \$13,000,000 total cost		
<b>Maximum Award Duration</b>	Up to 5 years (60 months)		
<b>Stage-specific Amount and Duration</b>	<b>Stage</b>	<b>Early PDEV (Pre-IND)</b>	<b>Late PDEV (IND-Enabling)</b>
	<b>Amount</b>	\$5,500,000	\$7,500,000
	<b>Duration</b>	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			
<b>Applicant Organization</b>	Only non-profit or for-profit organizations that meet CIRM's definition of a California Organization are eligible to apply		
<b>Applicant PI</b>	The PI must commit a minimum of 15% effort		
<b>Project Manager</b>	The project team must include an experienced project manager at a minimum 50% effort		
<b>Co-funding</b>	<b>Unpartnered Non-Profit</b>	<b>Non-Profit with For-Profit Partner</b>	<b>For-Profit</b>
	None Required	20% of allowable project costs	20% of allowable project costs
The minimum co-funding requirement may be fulfilled by cash-based or warrant-based co-funding			
<b>Stage Readiness</b>	The application must provide data demonstrating that reproducible disease-modifying activity was achieved with the proposed candidate		
SCHEDULES AND DEADLINES			
<b>Application Due Date</b>	Once per year		
<b>GWG Selection</b>	Approximately 45 days after application deadline		
<b>GWG Review</b>	Approximately 90 days after GWG Selection		
<b>Award Approval</b>	Approximately 60 days after GWG Review		
<b>Start Date</b>	Must be ready to start award activities within 90 days of award approval		

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### 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](mailto:preclinical@cirm.ca.gov). For questions related to the review and approval of applications, contact [review@cirm.ca.gov](mailto: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.

### ***Program Guiding Principles***

The PDEV program is designed to strengthen the clinical pipeline by advancing innovative stem cell and genetic therapies with the potential for transformative clinical impact, while proactively addressing barriers to patient access and affordability.

To achieve this objective, the PDEV portfolio will prioritize programs that:

- Have potential to deliver transformative improvements in patient outcomes by leveraging cutting-edge therapeutic technologies.

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- Address known barriers to access and affordability of stem cell-based and genetic therapies.
- Broadly address both prevalent and rare diseases affecting Californians.

PDEV Guiding Principles are applied across the application life cycle to build an award portfolio of scientifically meritorious projects that will achieve the SAF Impact Goals.

## 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 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

\*Refer to CIRM Access and Affordability Planning Requirements for definitions of key terms, program-specific requirements, and evaluation criteria.

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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. ¶

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✗	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.

**Provisional timetable**

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

PROVISIONAL TIMETABLE	
Applications <b>Open</b>	Once per year
Applications <b>Due</b>	Approximately 60 days after applications open
Grants Working Group (GWG) <b>Selection</b>	Approximately 45 days after application deadline
<b>GWG Merit Review</b>	Approximately 90 days after GWG Selection
<b>ARS Award Approval</b>	Approximately 60 days after GWG Merit Review

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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.

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**Award Start**

90 days after award approval

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**Grants Working Group Selection**

If the number of applications submitted exceeds the volume that can reasonably be reviewed by the GWG panel, the Grants Working Group (GWG) will conduct an initial screening to identify those applications that best align with the PDEV program objectives.

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Selection for advancement to full panel discussion will be based on:

- Alignment with the PDEV Guiding Principles; and
- The value proposition review criteria defined in the 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.

**Application Review Subcommittee Award Approval**

The CIRM Team will provide analysis and recommendations to support the ARS in making informed funding decisions that build a portfolio of scientifically meritorious projects aligned with the SAF Impact Goals.

For each relevant application, the CIRM Team will prepare a Guiding Principles summary that will inform the CIRM Team's Funding Recommendation to the ARS. In developing its recommendation, the CIRM Team will consider:

- Available program budget;
- GWG score and reviewer comments;
- The Guiding Principles summary;
- Prior awardee performance (if applicable); and
- Any material new information available to CIRM following GWG review.

**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

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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"

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