CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Preclinical Development (PDEV) Frequently Asked Questions (FAQ)

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Foreword

We strongly advise that all potential applicants carefully read the Program Announcement and other documents linked in the section below. In addition, please open an application in the grants management system and review all of the uploads that are required for submission. Many questions can be answered with the information provided in those documents. If you have questions after review of these materials, you may email the Preclinical Development team at preclinical@cirm.ca.gov.

Additional Resources for Applicants

- PDEV Program Announcement (PA)
- CIRM's Funding Opportunities: Common Requirements and Definitions
- CIRM's Data Sharing and Management Requirements
- CIRM's Patient Access Planning Requirements
- CIRM's Allowable Costs and Co-funding FAQ
- CIRM's Commercialization Rights Primer (IP, Revenue Sharing, Pricing, Access, March-in Rights)
- CIRM's Grants Administration Policy for Clinical Stage Projects

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Project Scope

1. **What is the distinction between early and late PDEV? Are these separate programs that applicants have to apply to one after the other? Can an applicant only apply to the "Early PDEV"?**
   Early PDEV (Pre-IND) and Late PDEV (IND-enabling) refer to the two stages of preclinical development encompassed by PDEV awards. Projects that meet the candidate readiness eligibility criteria may request CIRM funding for Early and/or Late PDEV activities to achieve the expected outcome of IND clearance with the FDA for the proposed therapy. Applicants may not request funding solely for Early PDEV activities that won't achieve the expected award outcome. Applicants may request funding solely for Late PDEV activities if FDA pre-IND feedback has already been obtained for the proposed project.

2. **Are animal studies required for demonstrating disease modifying activity in order to meet the candidate readiness eligibility requirement?**
   No, there is no requirement for animal studies to demonstrate disease modifying activity; applicants are welcome to use any assay to demonstrate disease modifying activity along with a narrative why their studies indicate the potential to correlate with clinical benefit.

3. **What candidate optimization activities are within scope for PDEV funding?**
   Within the first six months of a PDEV award with early phase activities, applicants are allowed to propose and perform studies that could improve their therapeutic candidate. Allowable activities include, but are not limited to, changing the cell/tissue source, gene engineering/editing components, and/or delivery mechanism. At the

end of the six-month period, the PI is required to select the final therapeutic candidate to move forward towards IND clearance; if candidate optimization activities do not identify another candidate, the PI will be expected to advance the originally proposed candidate.

4. Does CIRM have a preference for early or late PDEV programs? Do these program stages compete against each other in the same cycle?

CIRM does not have a preference for early or late PDEV programs. Both types of applicants will be competing for funding approval in any given application cycle.

5. What patient access planning activities do I need to have completed at the time of application?

At the time of application, applicants must describe any progress to date on patient access activities, commercialization and market access activities as listed in the CIRM Patient Access Planning Requirements document. Applicants will also be required to describe what progress on these activities they plan to make over the course of the

CIRM-funded project. Any proposed activities will be incorporated into PDEV award operational milestones, and applicants will be required to report progress on commercialization and market access activities throughout the duration of the project.

6. Can PDEV funding support a program intended to solely conduct clinical trials outside the US?

The expected outcome of a PDEV award is IND-clearance from the FDA to begin clinical trials in the United States.

7. What are some examples of "trial start-up activities" that are within scope for funding in the PDEV program?

Trial start-up activities are allowable over the course of a PDEV award and can extend up to 6 months after IND clearance. Examples of trial start-up activities include, but are not limited to, site selection/qualification/contracting/activation/training, IRB and regulatory submissions, CRO selection and contracting, development of patient outreach/recruitment materials, etc. Conduct of a trial beyond start-up activities are not allowable costs. For example, patient recruitment, screening or enrollment are

not allowable costs. It is up to the applicant to propose a reasonable scope and budget for trial start-up activities.

Individual and Team Eligibility

8. Can non-PI (e.g., staff) apply for the PDEV program?

Please refer to CIRM's Common Requirements and Definitions document for CIRM's requirements for Principal Investigators.

9. Can an entity located in California but incorporated outside of California apply for CIRM PDEV funding?

The entity does not need to be incorporated in California to meet the California Organization eligibility requirement. Please refer to CIRM's Common Requirements and Definitions document for CIRM's definition of a California Organization.

10. What are the eligibility requirements for California subsidiaries of non-California parent organizations?

Please refer to CIRM's Common Requirements and Definitions document and CIRM's Allowable Costs and Co-Funding FAQ for additional details on California subsidiary eligibility requirements.

11. Can the PI on one application be key personnel on another?

Yes, however, please note that the individual must not exceed 100% effort combined across funded projects.

12. When does the applicant need to meet all the eligibility requirements?

At the time of application submission, applicant must demonstrate the ability to meet all eligibility requirements as described in the PDEV Program Announcement.

13. Can a California applicant that has licensed IP develop out-of-state be eligible?

Yes, if the California applicant meets the California Organization eligibility requirement. Please refer to CIRM's Common Requirements and Definitions document for CIRM's definition of a California Organization.

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Application and Review Process

14. Are pre-application consultations required? How do I schedule one?

Pre-application consultations are not required before submitting an application. However, each applicant may receive a 30-minute consultation with the PDEV team. Do review the PA, the proposal template and the online application carefully before meeting with the PDEV team to get answers to clarifying questions. Please visit our program page to request a consultation.

15. How will my application be reviewed after submission?

Please refer to the Application Review Information section of the PDEV PA for a detailed description of the review criteria and process.

16. When is the next cycle of PDEV?

Please subscribe to our mailing list on our website: https://www.cirm.ca.gov/preclinical/ to be notified when the new cycle begins.

17. Can INTERACT meeting feedback be submitted after the application deadline?

Formal communications from/to the FDA can be appended to submitted applications. Email them to review@cirm.ca.gov as a single PDF document with a maximum one page cover letter explaining the relevance of the additional document(s) to the application.

18. Where can I learn more about PDEV application requirements?

Please refer to the Application Preparation and Application Review Information sections in the PA for application requirements.

19. How early should I obtain subcontract quotes for the application?

As stated in the Program Announcement, for any proposed subcontracts over $500,000, a tabulated summary of at least three proposals must be provided. CIRM recognizes that obtaining quotes can be a lengthy process and suggests that applicants may want to obtain quotes early. Applicants requesting Early & Late PDEV activities may provide reasonably justified estimates from sub-contractors for

Late PDEV activities (i.e. GLP studies, GMP studies, etc., that may be pending FDA pre-IND feedback).

Budget, Award Duration, and Administration

20. Are activities performed by third party out-of-state collaborators (including international) who do not own IP rights allowable?

CIRM funds cannot be used for "research" being conducted outside of California. To define what constitutes "research", our policy identifies the most common characteristics of what constitute a 3rd party subcontract for research activities: one in which the 3rd party retains IP or independent publications rights arising out of their portion of the CIRM-funded project. If a 3rd party retains such rights, their work would not be considered an allowable cost. If the 3rd party waives both its IP and independent publication rights, then CIRM can fund such work.

21. Is there a cap on the total budget that can be subcontracted to an out-of-state contractor (e.g., CDMO, CRO, consultants)?

There is not a formal cap on how much of the budget can be subcontracted out-of-state, as long as those contracts meet our requirements discussed in question 20.

Data Sharing and Management

22. What are some examples of shareable data in the PDEV program?

Examples of potentially sharable data include applicable data from preclinical in vitro studies, in vivo studies, process development, assay development, etc. Please refer to the PDEV Program Announcement and CIRM's Data Sharing and Management Requirements document for additional information on requirements.

Knowledge Sharing

23. How do I satisfy the knowledge sharing requirement?

CIRM expects that knowledge resulting from PDEV awards will be shared within the CIRM network to drive efficiency and reduce potential roadblocks by leveraging proven processes, study designs, and regulatory pathways to optimize development and eliminate redundant efforts. Sharing learnings with other CIRM awardees will

improve product development progression and support a risk-based approach to both planned and unexpected changes throughout the preclinical drug development process while retaining IP and patient/donor privacy. At the time of application submission, PDEV applicants are asked in the Data Sharing Overview section of the application to certify to work with CIRM to align with knowledge sharing processes as they are implemented.

Commercialization Planning

24. Can you elaborate on the expectations for commercial planning activities at the Preclinical Development award?

This section of the application proposal is intended to capture current status of commercialization planning as well as plans for progress over the CIRM-funded project period. The Commercialization Plan described in the application will serve as the starting point for updates on progress over the course of the CIRM award.

Applicants should do their best to complete the commercialization planning section for the listed activities; the proposal template provides suggested sub-activities as helpful reference. It is acceptable for an applicant to not have started certain activities. All applicants should describe how they plan to make progress on patient access planning activities (market landscape and market access strategy) over the CIRM-funded project period.

Helpful resources for reference:

- *NIH Intramural Research program Access Planning Policy - https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-062.html*
- *NIH SBIR/STTR Resources for writing the commercialization plan – https://nida.nih.gov/sites/default/files/Commercialization_Plan_Guide.pdf*
- *NCI SBIR/STTR Resources for writing the commercialization plan – https://sbir.cancer.gov/commercialization/workshops-webinars/peer-learning/strong-commercialization-plan*
- *NHLBI Small Biz Hangout: Writing Your Phase II Commercialization Plan*

Co-funding

25. How does warrants-based co-funding work?

Please refer to CIRM's Allowable Cost and Co-funding FAQ.

26. Does the 20% co-funding requirement for for-profit applicants and for-profit partners of non-profit applicants need to be met at the time of application stage?

At the time of application submission, Applicant must demonstrate the ability to meet the co-funding requirement as described in the PDEV Program Announcement. Please refer to CIRM's Allowable Cost and Co-funding FAQ for more details.

Contact

27. If I have questions about the PDEV program scope, who do I contact?

Please email us at preclinical@cirm.ca.gov.

28. If I have questions about the review process, who do I contact?

Please email us at review@cirm.ca.gov.

29. If I have questions about grants administration, who do I contact?

Please email us at GrantsManagement@cirm.ca.gov.