Preclinical Development (PDEV) Frequently Asked Questions (FAQ)

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ADDITIONAL RESOURCES FOR APPLICANTS

- The Pre-submission form is available in our grants management portal
- PDEV Program Announcement (PA)
- CIRM's Funding Opportunities: Common Requirements and Definitions
- CIRM's Data Sharing and Management Requirements
- CIRM's Access and Affordability 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
- PDEV Webinar can be found on our website

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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 access and affordability 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 access and affordability activities and commercialization and market access activities as listed in the Access and Affordability 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 access and affordability 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.

INDIVIDUAL AND TEAM ELIGIBILITY

6. **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.

7. **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.

8. **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.

9. **Can the PI on one application be a key personnel on another?**

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

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

    At the time of pre-submission, the applicant must certify that it will be able to meet all the eligibility requirements (e.g., PI, California org, Co-funding) if invited for a full application. At the time of application submission, applicant must demonstrate the ability to meet all eligibility requirements as described in the PDEV Program Announcement.

11. **Can a California applicant that has licensed IP developed 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.

PRE-SUBMISSION PROCESS AND REVIEW PROCESS

12. **Is there a limit to how many pre-submissions can be submitted?**

    Multiple PIs from the same institution may submit a pre-submission, however, there is a limit of 1 pre-submission per PI per cycle.

13. **How binding is the pre-submission proposal?**

    The project described in the full application should largely reflect the project that was presented in the pre-submission proposal. During the formal eligibility assessment of full

applications, CIRM will verify that the candidate and disease indication are the same as what was indicated in the pre-submission.

14. Is there a page limit to the DMA table in pre-submission?

The template table for studies of disease modifying activity does not specify a length. This is because we expect projects at different stages of preclinical development to be submitted. Some applicants will have many DMA studies, some will have few. However, CIRM staff will need to read and digest the information in your table efficiently, and this is what should guide you as you work. The Sample Entry (highlighted green in the template) is a good benchmark for word count per study. Do not include every single study of surrogates/analogs independently if this makes the table unwieldy. CIRM is most interested in studies demonstrating DMA with the candidate or its closest surrogates/analogs. Remember that at least one entry must be a completed study demonstrating reproducible disease modifying activity of the candidate in an in vitro or in vivo preclinical model that is relevant to the target indication.

15. How will the pre-submissions be evaluated?

Please refer to the Pre-submission Components and Evaluation section of the Program Announcement for information on how PDEV pre-submissions are evaluated.

16. What does CIRM consider as a Central Nervous System (CNS) disease?

A project is generally categorized as treating a disease or condition of the brain or central nervous system (CNS) if the therapeutic candidate is intended to primarily act upon and ameliorate conditions involving aged, damaged, diseased, or defective tissues or impaired functionalities within the brain, spinal cord, retina, or optic nerve. If you need clarification on a specific disease indication, please email preclinical@cirm.ca.gov.

17. When is the next cycle of PDEV?

The next PDEV cycle will open in Fall 2025 with applications due in early 2026. Please subscribe to our mailing list on our website: https://www.cirm.ca.gov/preclinical/ to be notified when the new cycle begins.

18. 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.

19. 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.

20. When will applicants be invited to submit a full application, and when will funding decisions be released?

Please refer to the provisional timetable in the PA for approximate timeline.

BUDGET, AWARD DURATION AND ADMINISTRATION

21. 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.

22. How many awards are expected to be approved?

CIRM anticipates funding between 12-21 PDEV awards in FY25-26, contingent on the ratio of Early PDEV and Late PDEV applications recommended for funding.

23. 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 21.

DATA SHARING AND MANAGEMENT

24. Can the Data Manager and Project Manager roles be "TBD" at the point of pre-submission?

Yes. At the time of pre-submission, the applicant certifies that all PDEV application elibility requirements, including project manager and data manager commitments, will be met if invited to submit an application.

25. 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

26. 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.

CO-FUNDING

27. How does warrants-based cofunding work?
Please refer to CIRM's Allowable Cost and Co-funding FAQ.

28. 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 pre-submission or application stage?

At the time of pre-submission, the Applicant must certify that it will be able to meet the co-funding eligibility requirement if invited for a full application. 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

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

Please email us at preclinical@cirm.ca.gov

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

Please email us at review@cirm.ca.gov

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

Please email us at GrantsManagement@cirm.ca.gov