CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Clinical Development (CLIN2) Frequently Asked Questions (FAQ)

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 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 request a consultation with the Clinical Development team by emailing clinical@cirm.ca.gov.

RESOURCES FOR APPLICANTS

- The CLIN2 Application is available in CIRM's Grants Management System
- CLIN2 Program Announcement (PA)
- CLIN2 Quick Guide on the Application Selection Process
- CIRM's Funding Opportunities: Common Requirements and Definitions
- CIRM's Data Sharing and Management Requirements
- CIRM's 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. **Are there specific diseases prioritized for this funding opportunity?**
   Applications addressing any disease area are welcome to apply and are eligible for consideration.

2. **Does the CLIN2 program support clinical studies in healthy volunteers?**
   CIRM will support studies in healthy volunteers only if they are part of the same protocol as an interventional study in patients. The FDA must have cleared both the healthy volunteer and interventional parts of the protocol at the time of the CLIN2 application submission.

3. **Are protein-based therapeutics an accepted modality?**
   Protein-based therapeutics are eligible if they meet the requirements described under "Regenerative Medicine-based Therapeutics" in CIRM's Common Requirements and Definitions. This definition includes descriptions of eligible stem cell-based and genetic therapies. If you have questions about the eligibility of your proposal, please request a consultation with the Clinical Development team (clinical@cirm.ca.gov).

4. **Can the CLIN2 program fund clinical trials which have already been initiated at the time of grant application?**
   Yes.

5. **Can the CLIN2 program accept applications which support BLA enabling work or submission, including manufacturing costs for PPQ activities?**
   Yes, CLIN2 awards can be used to support BLA enabling work and submission.

APPLICANT ELIGIBILITY

6. **Is the CLIN2 program open to non-California based organizations?**
   Yes. For more information, please see the Allowable Costs and Co-Funding FAQs available on the CLIN2 web page.

7. **Are CA-subsidiaries of non-CA organizations eligible?**
   Yes, A California-domiciled wholly owned subsidiary of a non-CA organization can qualify as a CA organization if it meets the requirements of a CA organization with respect to Employment and Payroll; Management of Award Activities; and Intellectual Property Rights as set forth in the Program Announcement and CIRM Common Requirements and Definitions document.

8. **In order to qualify as a California organization, does my organization need to satisfy the requirements of a California organization at the time of application?**
   Yes, all eligibility requirements need to be met at the time of application.

APPLICATION AND REVIEW PROCESS

9. **Can I schedule a meeting with CIRM personnel before submitting my application?**
   Each applicant is highly encouraged to request an in-depth consultation by emailing clinical@cirm.ca.gov. You will then be provided a 'Consultation Intake Form' to submit your specific questions to the Clinical Development team. Once the form is submitted, CIRM will follow up with a direct written response where appropriate or will provide an opportunity to schedule a consultation with an available Science Officer.

10. **How will my application be reviewed after submission?**
    Please refer to the Application Review Information section of the CLIN2 PA for a detailed description of the review criteria and process.

11. **How many applications will be fully reviewed by the Grants Working group?**
    We anticipate approximately 10 applications will be reviewed per cycle.

12. **Do vendor contracts need to be signed and executed prior to submission of the grant application?**
    Vendor contracts do not need to be executed before submitting the application unless enrolling for an ACTIVE trial. Quotes should be uploaded for all vendor costs for which you seek CIRM funding, whether signed or not. If a quote is unavailable, detail the basis of your funding estimate in the budget justification.

13. **For the budget, can we use estimates for CRO services if we don't have firm figures yet?**
    For an applicant submitting during enrollment for an ACTIVE trial, a signed and active CRO [and any other critical] contract must be in place at the time of application.
    Vendor contracts for NEW trials do not need to be executed before submitting the application. You would upload quotes for all vendor costs for which you seek CIRM funding, whether signed or not. If a quote is unavailable, detail the basis of your funding estimate in the budget justification.

14. **Are patient access activities required to be completed prior to the start of the grant, or during the course of the award?**
    The required patient access activities depend on the stage of the program. Some activities will be required to be completed at the time of the submission while others should be accomplished during the course of the award. For more information see the Access Planning Requirements.

15. **At what stage should the proposal be submitted, after IND clearing?**
Please refer to the Eligibility section of the PA.

16. **Can I amend my clinical protocol with the FDA after submission of the CLIN2 application, but prior to receiving a funding decision?**
No, any amendment to the clinical protocol during the application review period will immediately make your application ineligible for that funding round.

17. **Will you please clarify the requirements to submit copies of the IND submission and amendments, i.e. what contents are needed?**
Applicants are required to provide copies of all regulatory correspondence related to your project. Applicants do not need to submit the entire IND, but it is recommended. Submit required sections as a PDF or multiple PDFs if needed. For more information, please reach out to our Clinical Development team (clinical@cirm.ca.gov). Applicants must also provide a regulatory correspondence table of contents to enable reviewers to navigate the regulatory correspondence uploads. This table of contents must refer to the CIRM application portal generated filenames for each of your documents and annotate key pages in the correspondence. Therefore, this document must be generated after all regulatory correspondence has been uploaded to your application.

18. **Does AOO have to be a different person from the PI?**
The PI and AOO cannot be the same person, unless there is a compelling reason. For more information, please reach out to our Clinical Development team (clinical@cirm.ca.gov).

19. **Will there be a preference given to grant applications submitted prior to the submission deadline?**
No, early applications do not receive preferential status.

20. **For an investigator-initiated grant, what are the financial requirements of the company that owns the drug/clinical product?**
Please refer to the Co-Funding Requirements section of the CLIN2 Program Announcement. Set up a consultation with Clinical Development team (clinical@cirm.ca.gov) to discuss specific circumstances.

AWARD APPROVAL AND ADMINISTRATION

21. **How are project activities that are completed between submission and approval treated?**
Reference 'Pre-Award Costs' in the Grant Administration Policy Clinical Stage Projects for more information.

22. **Are the grant funds distributed evenly across all open submission periods, or will it depend on the number of proposals received in the first round?**

The CLIN2 program budget is approved on an annual basis covering four award cycles. While we do aim to distribute the budget across cycles to cover the fiscal year, the Application Review Subcommittee of CIRM's board makes final funding decisions.

23. **How many CLIN2 awards does CIRM anticipate funding in fiscal year 26/27?**
We are targeting funding 9-16 projects this fiscal year (July 1, 2026 - June 30, 2027).

24. **What is the award amount if we have a phase 1/2 trial?**
For any first in human phase 1 trial, the maximum award amount is $8M in the case of a for-profit and $12M for a not-for-profit. For any trial that is subsequent to a first-in-human trial, the maximum award amount is $15M.

25. **Can CIRM provide more information about royalties?**
Please see the Commercialization Rights Primer.

26. **Is there a loan agreement template available to review the terms?**
No, there is no agreement template. See the Commercialization Rights Primer for information about loan conversion options.

27. **What are the funding cycles for 2026 & 2027 (e.g., when are future dates that the CLIN2 grant will be accepting proposals)?**
It is anticipated that the CLIN2 opportunities will be offered quarterly. When the next deadlines are set, they will be posted on the CLIN2 website. We recommend that you subscribe to CIRM's email notifications to get alerts of new CIRM program deadlines.

28. **Are costs from a non-California site allowable for a California-based organization that operates at least one California site?**
Yes. For more information, please refer to definition of allowable costs in the Allowable Costs and Co-Funding FAQ.

CO-FUNDING

29. **Can you explain how co-funding works for for-profit companies? Should the total budget be 30% higher than what is requested?**
Please see the Allowable Costs and Co-Funding FAQs available on the CLIN2 web page. The total project costs must be co-funded by the applicant at the minimum percentages listed in the Program Announcement. The total budget must include the minimum co-funding portion in addition to the amount requested from CIRM.

30. **Can you please elaborate on the stock warrant option for co-funding by for-profit organizations (including the for-profit partner of a non-profit applicant)?**
Please refer to the Warrant-Based Co-Funding Requirement section of the Allowable Costs and Co-Funding FAQ. If you have reviewed that document and still have specific questions, consult legal@cirm.ca.gov.

31. **When is my organization considered to have a 'partner'? Why do I need to declare a partnership?**
    Please consult the CIRM's Common Requirements and Definitions to find the definition of a 'partner'. An organization is required to accurately declare a partner because it impacts your co-funding requirements. Not for Profit applicants that have a For Profit partner are subject to the same co-funding requirements as a For Profit applicant. For more details, see the Eligibility section of the CLIN2 PA.

32. **How do I properly document that I have co-funding and contingency funds available to my project for CIRM?**
    You should document the availability of funds, noting the specific co-funds and contingency funds proposed to be available in the application in the letters of support from the relevant funder(s). For-profit organizations will also need to submit a completed solvency worksheet.

CONTACT

33. **If I have questions about the CLIN2 program, who do I contact?**
    Please email us at clinical@cirm.ca.gov.

34. **If I have questions about the review process, who do I contact?**
    Please email us at review@cirm.ca.gov.

35. **If I have questions about grants administration, who do I contact?**
    Please email us at GrantsManagement@cirm.ca.gov.