CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Clinical Development (CLIN2) Frequently Asked Questions (FAQ)

ADDITIONAL RESOURCES FOR APPLICANTS

- The CLIN2 Application is available in CIRM's grants management portal (grants.cirm.ca.gov)
- CLIN2 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
- CLIN2 Webinar can be found on our website

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PROJECT SCOPE

1. **Are there specific diseases prioritized for this grant?**
   Applications addressing any disease area are welcome to apply and are eligible for consideration.

2. **Does CIRM CLIN2 support a healthy volunteer phase 1a if coupled with phase 1b in target patient population?**
   Yes, but as mentioned in the question, only in conjunction with an interventional trial in the target patient population. (CIRM will also allow associated natural history studies).

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 doubts about the eligibility of your proposal, please reach out to our Clinical Development team (clinical@cirm.ca.gov).

4. **Are there limitations for CIRM to fund phase 3 clinical trials already approved by the FDA and initiated?**
   CIRM can fund phase 3 trials, including those already initiated.

5. **What type of clinical trials will be funded?**
   All stages of clinical trials are eligible for funding.

6. **Can the CLIN2 program accept applications which support BLA enabling work or submission?**
   Yes, CLIN2 awards can be used to support BLA enabling work and submission.

APPLICANT ELIGIBILITY

7. **Is the CLIN2 program open to non-California based non-profits?**
   Yes. Please refer to the Allowable Costs and Co-Funding FAQs link on the CLIN2 web page.

8. **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.*

9. **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. To be considered a California organization, your organization must meet all the necessary requirements at the time you submit your application.

APPLICATION AND REVIEW PROCESS

10. **Can I schedule a meeting with CIRM personnel before submitting my application?**
    Each applicant will have the opportunity to request an in-depth consultation via the CLIN2 Consultation Intake Form. After 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.

11. **How will the preference list be used?**
    These preferences may be taken into consideration at two stages of the application life cycle: first, during a pre-review qualification step to prioritize which applications go to full review, and second, during consideration of recommended projects by the Application Review Subcommittee of CIRM's governing board. The scientific review of applications is conducted by CIRM's Grants Working Group. When the number of submitted applications exceeds the number that can be reviewed, the qualification process is triggered to prioritize those that will go to scientific review. This process assigns points to each of the objective PA preferences and assigns a score to each application. The top scoring applications within the GWGs capacity, approximately seven, then proceed to review. The preferences may also be used by the Application Review Subcommittee of CIRM's board in making funding decisions.

12. **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. For more information, please reach out to our Clinical Development team (clinical@cirm.ca.gov).

13. **How many applications will be reviewed?**
    We anticipate approximately 7 applications will be reviewed per cycle.

14. **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.

15. **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.

16. **Are Access and Affordability activities required to be completed prior to the start of the grant, or during the course of the award?**
    The required Access and Affordability 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. Please see the link to "Access and Affordability Planning Requirements" on the CLIN2 Awards webpage.

17. **At what stage should the proposal be submitted, after IND clearing?**
CLIN2 applications should be submitted after the IND has been cleared to proceed. One exception is in the case of a project progressing from an active earlier stage CIRM award. In this case the CLIN2 application can be submitted to CIRM after the IND is submitted to the FDA, while waiting for the FDA clearance to proceed. The application will be considered for review in that application cycle as long as the applicant provides documentation from FDA to confirm that the IND and clinical protocol are safe to proceed within 30 days of submission of the CLIN2 application.

18. **What are the Accessibility and Affordability requirements for a phase 1b study that is not first in human?**
A phase 1b that is not First in Human would be treated as a phase 2. Please see the link to "Access and Affordability Planning Requirements" on the CLIN2 Awards webpage.

19. **How are industry partnerships viewed in funding considerations?**
Industry partnerships are highly encouraged, both as sources of co-funding and to progress the therapy towards commercialization.

20. **We are using an eCTD system to submit the IND, how do we submit the entire eCTD (which is hundreds of pages) into the CIRM web portal for IND submission documents?**
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).

21. **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).

22. **Will there be a preference given to grant applications submitted prior to the June 30th deadline?**
No, early applications do not receive preferential status.

23. **For an investigator-initiated grant, what are the financial requirements of the company that owns the drug/clinical product?**
If an investigator has a for-profit partner, 30% co-funding is required for a first in human trial and 50% co-funding is required for all subsequent trial phases. Please set up a consultation with Clinical Development team (clinical@cirm.ca.gov) to discuss specific circumstances.

24. **Are you planning on implementing a pre-submission system for CLIN2, similar to that of the PDEV and DISC4 programs?**
    No, CLIN2 will not have a pre-submission process.

AWARD APPROVAL AND ADMINISTRATION

25. **How are project activities that are completed between submission and approval treated?**
    Costs for project activities in an application can only be incurred on or after the date of ICOC approval, i.e., milestones or activities completed prior to approval are not allowable costs. Operational Milestones are a feature of the Notice of Award and are subject to negotiation after ICOC approval based on CIRM's sole discretion. For the contracting period between ICOC approval and the award start date, an Awardee may incur costs against the award, at its own risk, to cover necessary and allowable costs. Reference page 31 section C on Pre-Award Costs in the Grant Administration Policy Clinical Stage Projects for more information.

26. **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. If CIRM receives more applications than can be reviewed in a given cycle, there is an additional qualification process described in the PA which will be implemented. 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.

27. **Is the CLIN2 program planning to select 15-20 therapies to advance to late-stage trials during fiscal year 25/26?**
    One of CIRM's Strategic Allocation Framework (SAF) goals is to advance 15-20 therapies to late stage trials; the SAF is a multiyear framework. We are targeting funding 9-16 projects this fiscal year (July 1 2025 - June 30 2026).

28. **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.

29. **Will CIRM provide funding for BLA enabling studies, including manufacturing costs for PPQ activities?**
    Yes, CIRM can fund BLA enabling studies as part of a Phase 3 clinical trial.

30. **Can CIRM provide more information about royalties?**
    Please see the Commercialization Rights Primer available on the CLIN2 web page.

31. Is there a loan agreement template available to review the terms?
No, there is no agreement template. See the Commercialization Rights Primer available on the CLIN2 web page for information about loan conversion options. Upon payment of the conversion, the revenue sharing burden falls away. All other terms in the Notice of Award still apply.

32. What are the funding cycles for 2025 (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 sign up for email notifications of new CIRM program deadlines (sign up link is available on the program landing page).

33. Are costs associated with a non-California site for a California-based organization which has one California site allowable costs?
Yes, these costs are allowable. For a California Organization, Allowable Project Costs include:
i. The per subject share of the costs of clinical and non- or pre-clinical research activities that are directly attributable to the treatment of patients enrolled in the proposed clinical trial; and
ii. Costs of manufacturing activities for a subsequent clinical trial, contingent on 1) an interim evaluation by CIRM and a panel of independent experts of the clinical trial data to date, and 2) provision of 50% co-funding for this activity, if co-funding is required for the overall award.

CO-FUNDING

34. 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 Cofunding FAQs available on the CLIN2 web page.

35. Can you please elaborate on the stock warrant option for co-funding by for-profit organizations?
Please consult legal@cirm.ca.gov

CONTACT

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

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

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