

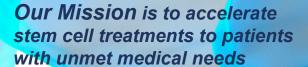
Clinical Trial Stage Projects CLIN 2

Everyone

Everywhere

Can Apply

For Funding



CLINICAL

Partnering Opportunity For Clinical Trial Stage Projects

CLIN₂

Program Objective

To create a **highly competitive** partnering opportunity for promising stem cell-based projects to accelerate the completion of a **clinical trial** for a stem cell-based therapy that addresses an unmet medical need.

Who can apply?

California Based Organizations (for-profit & non-profit):

- May use CIRM funds for eligible project costs incurred both in California and outside California.
- California organizations must have >50% of its employees located in, and paid in, the state of California, and manage the award activities from the California location.

Non-California Based Organizations (for-profit & non-profit):

- CIRM funding can be used only for allowable expenditures incurred within California.
- Applicant is expected to demonstrate by the application deadline a commitment of funds from other sources for project activities outside of California.



Award Application Information

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Supported Activities

- Activities necessary for the conduct and completion of a Phase 1, Phase 2, or Phase 3 clinical trial under a single IND or IDE
- Manufacturing of product or the device to supply or conduct the proposed clinical trial
- Exploratory biomarker testing of samples from the clinical trial
- Assay development (e.g. potency assay)
- Stability testing
- Regulatory activities required for approval of the drug or device

Deadline and Schedule

| Applications Due | 2:00 pm (PDT/PST) on last business day of each month |
|----------------------------|--|
| Scientific Review | ~60 days post submission |
| CIRM Board Review/Approval | ~90 days post submission |
| Award Start | Within 45 days of award approval |

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Apply When You're Ready

Project Eligibility Requirements

- Must be ready to initiate work on the funded project within 45 days of approval
- Must propose a single clinical trial using a stem cellbased therapy or a device for use with a stem cellbased therapy
- Must have regulatory approval to proceed with proposed trial
- Must include a project manager
- Co-funding requirements

| Applicant Type | Phase 1 | Phase 2 | Phase 3 |
|----------------|---------|---------|---------|
| Non-Profit | None | 40% | 50% |
| For-Profit | 30% | 40% | 50% |

- Must adhere to requirements for clinical trial sites in California
- For-profit organizations must demonstrate solvency

For application and instructions: cirmca.gov/clin2awards

Questions? gsambrano@cirm.ca.gov

