Clinical Trial Stage Projects
CLIN 2

Everyone
Everywhere
Can Apply
For Funding

Our Mission is to accelerate stem cell treatments to patients with unmet medical needs
Partnering Opportunity For Clinical Trial Stage Projects

CLIN 2

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.
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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Timeline</th>
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</thead>
<tbody>
<tr>
<td>Applications Due</td>
<td>2:00 pm (PDT/PST) on last business day of each month</td>
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<tr>
<td>Scientific Review</td>
<td>~60 days post submission</td>
</tr>
<tr>
<td>CIRM Board Review/Approval</td>
<td>~90 days post submission</td>
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<tr>
<td>Award Start</td>
<td>Within 45 days of award approval</td>
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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 cell-based therapy or a device for use with a stem cell-based therapy
- Must have regulatory approval to proceed with proposed trial
- Must include a project manager
- Co-funding requirements

<table>
<thead>
<tr>
<th>Applicant Type</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Profit</td>
<td>None</td>
<td>40%</td>
<td>50%</td>
</tr>
<tr>
<td>For-Profit</td>
<td>30%</td>
<td>40%</td>
<td>50%</td>
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- 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