

## **FAQs on the Clinical Development (CLIN2) Program Qualification Process**

### **1. Why is a qualification process needed?**

The demand for CIRM funds from prospective awardees significantly exceeds the number of projects that CIRM is able to support. CIRM's process for evaluating clinical stage applications is known to give careful consideration to each proposal and provide opportunities for improvement. A large number of applications can overwhelm this established process of review, impacting the rigor of evaluation and the quality feedback that underpins applicant's opportunities for improvement. Unlike for NIH, CIRM is limited to 15 scientific grants working group members per review. Therefore, applying the qualification step to prioritize applications that are most aligned with CIRM goals and program priorities provides an added mechanism to manage the number of applications entering the system while maintaining the rigor of the process.

### **2. How does qualification differ from eligibility?**

To be "eligible" an application must meet the specific eligibility criteria described in the PA. These are strict requirements that determine whether CIRM can or cannot accept an application under the funding opportunity. An eligible application then undergoes a qualification assessment to determine the number of favored qualities, referred to as preferences, that prioritize it over other competing applications based on a point system. Applications with higher qualification scores are more likely to proceed to scientific review. An eligible application may or may not qualify, but an ineligible application cannot be considered for CIRM funding.

### **3. How many opportunities do I have to qualify?**

If an application does not qualify for scientific review in the current round, you may apply for a future round.

### **4. Who determines whether my application qualifies?**

Applications will be scored on objective criteria by CIRM review team staff members and on scientific review criteria by Grants Working Group experts as needed in the case of a tie for the 7<sup>th</sup> review position (see below). Ultimately, the total points earned and the relative rank against other applications in the pool will determine which applications qualify.

## 5. What are the qualifying criteria?

CIRM staff will use the CLIN2 PA preference areas as the qualifying criteria. For the 2025-26 fiscal year, CIRM staff will prioritize applications that:

- Develop pluripotent stem cell-derived therapies
- Develop in vivo genetic therapies
- Develop therapies using non-viral nucleic acid delivery
- Are projects addressing diseases of the brain and CNS
- Are applications from California organizations
- Are projects progressing from CIRM-funded IND-enabling or earlier phase clinical trial awards
- Are projects with Fast Track, RMAT or Breakthrough designations
- Are projects proposing pivotal clinical trials (as agreed-to by the FDA)

If objective scores are tied for the seventh review position, CIRM GWG will prioritize the tied applications based on the following criteria, which are a subset of the current value proposition scientific review criterion in the CLIN2 PAs. Reviewers will:

- Assess the therapy's potential to provide a meaningful and substantial improvement in clinical outcomes for the intended population as compared to therapies currently available or in trials (e.g., efficacy, safety, patient burden).
- Assess the expected impact of addressing the unmet medical need on patients, caregivers, and healthcare system.
- Evaluate the feasibility and practicality of the therapy's uptake by patients, healthcare providers and payors.

Reviewers will score applications based upon these criteria. The highest scoring applications from this evaluation will complete the review pool of seven.

## 6. How are the direct progression, CNS project and non-viral genetic therapy criteria used for qualification defined?

Projects must meet specific definitions to receive a point in the CLIN2 qualification process for the below preferences. Definitions follow below:

- **Direct Progression:** A direct progression event occurs when a prior CLIN1 or PDEV award addressed the same indication with the same therapeutic and the last activity or objective of that prior award aligns with start of current application. For example, a CLIN1 or PDEV prior award that had a goal to achieve an active IND would directly progress to a CLIN2 award for a first in human trial. Or a CLIN2 award to complete a first in human trial could progress to a phase 2, or subsequent phase 1, trial. Projects may occasionally directly progress from a TRAN1 award to a first in human CLIN2 award.
- **Projects addressing diseases of the brain and CNS:** 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.
- **Non viral genetic therapies:** Therapies using non-viral nucleic acid delivery are those in vivo genetic therapies that do not require viral vectors to deliver their nucleic acid payload.

**7. Will the criteria used for qualification remain the same or might they change later?**

The criteria that will be used are generally aligned with the goals of the current CLIN2 program as well as Prop 14. The ICOC may approve changes to these programs to ensure they are responsive to our overall strategic plan. Qualification criteria may therefore be adjusted to ensure continued alignment with any updated program goals and priorities.

**8. How are points assigned?**

For objective criteria, CIRM staff will assign one point for each of the criteria met with an extra point being assigned for pivotal trials.

In the case of a tie for the 7<sup>th</sup> review position, the GWG experts will score each of the three elements of value proposition described above under “5” on a scale of 1-50. The GWG experts will also assess if the application includes all necessary components for proper evaluation. Any application that is missing adequate information for review will be removed from consideration and the applicant will be asked to revise and resubmit.

**9. What can I do to maximize the chance of qualifying?**

- Contact the CIRM Clinical Development team ([clinical@cirm.ca.gov](mailto:clinical@cirm.ca.gov)) before completing an application for guidance and advice on developing a competitive application.
- Make sure your application is complete and provides all requested information including a complete CMC plan, FDA correspondence, and clinical protocol if applicable.
- Carefully consider whether your project is aligned with the goals and priorities of the CIRM and the CLIN2 PA

**Resources**

[CLIN2 Program Announcement](#)

[CLIN2 Webinar Recording](#)

[CLIN2 Webinar Slide Deck](#)

[CLIN2 Program FAQs](#)

For application questions, contact the CIRM Review office at [review@cirm.ca.gov](mailto:review@cirm.ca.gov).