

Quick Guide on the Clinical Development (CLIN2) Program Application Selection Process

Updated CLIN2 Application Selection Process

	Initial Volume Control/Selection Step	Tie Resolution Step
Previous Process - Qualification	If more than 7 applications are received: The 7 applications with the highest Preference scores proceed to full review by GWG	Ties for 7 th slot, if present, are broken by GWG assessment of Value Proposition
New Process - GWG Application Selection	Approximately 10 applications will be targeted for GWG discussion, but the actual number will be determined based on where a clear cut-off between scores falls.	Ties for final slot, if present, are broken by randomization

1. What is the new application selection process?

The CIRM Team will use program-specific guiding principles applied across the entire application lifecycle. These guiding principles translate the high-level impact goals under the Strategic Allocation Framework (SAF) into specific program objectives and are built into the application lifecycle from volume control, through scientific review, and CIRM Team recommendations to the Application Review Subcommittee (ARS). For CLIN2, these principles focus on the transformative impact of therapies, patient access, and broad disease representation. If the number of applications submitted exceeds the volume that can reasonably be discussed by the GWG panel, the GWG will conduct an initial screening to identify those applications that best align with the CLIN2 program objectives based on the criteria listed below. The GWG discussion and recommendations stage of review remains unchanged.

2. Why is a selection 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 gives careful consideration to each proposal. A large number of applications can overwhelm this established process of review, impacting the rigor of evaluation. Unlike for NIH, CIRM is

limited to 15 scientific grants working group members per review. Therefore, applying a volume control selection process step to prioritize applications that are most aligned with CIRM goals and program priorities provides a mechanism to manage the number of applications entering the system while maintaining the rigor of the process.

3. How does selection differ from eligibility?

To be “eligible” an application must meet the specific eligibility criteria described in the Program Announcement (PA). These are strict requirements that determine whether CIRM can or cannot accept an application under the funding opportunity. When the number of applications received exceeds the number that can be fully reviewed, applications then undergo the selection process by members of the Grants Working Group based on the selection criteria (see below). An application may or may not be selected by the Grants Working Group, but an ineligible application cannot be considered for CIRM funding.

4. What are the GWG criteria for selection?

Criteria for GWG selection of CLIN2 applications:

- The therapy’s potential to provide a meaningful and significant improvement in clinical outcomes compared to therapies currently available or in development.
- Impact of addressing the unmet medical need on patients, caregivers and the healthcare system.
- Feasibility and practicality of the therapy’s uptake by patients, caregivers, and the healthcare system.

5. How many opportunities do I have to advance my application?

If an application does not progress to/or is not selected in the current round, the applicant may apply for a future round.

6. Who determines whether my application proceeds to GWG discussion?

The Grants Working Group will assess applications and provide a weighted composite score based on selection and ranking by GWG members. Applications must also be deemed eligible by CIRM to progress to GWG discussion and recommendations.

7. How is a composite score calculated?

Applications are each given a composite score that combines two measurements from the GWG reviewers, selection and rank. The fraction of reviewers that selected the application measures the breadth of interest in the application, whereas the rank given by reviewers measures the intensity of interest by the reviewers. The two measurements are weighted 60% and 40%

respectively to prioritize the breadth of interest over the intensity of interest. Therefore, the formula to calculate the composite score becomes the following: $60\% \times \text{Selection points} + 40\% \times \text{Rank points}$. The composite numerical score will range from 0 to 1, where a 1 is a perfect score.

8. What can the applicant do to maximize the chance of proceeding to GWG discussion?

- Contact the CIRM Clinical Development team (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, clinical protocol, Access plan and Activities Based Budget.
- Carefully consider whether your project is aligned with the goals and review criteria of the [CLIN2 Program Announcement](#).

The full details of the transition are in the [Board Memo](#). Other resources available include an [Executive Summary](#), [CIRM's Board Presentation Deck](#), and the [YouTube Recording of the Application Selection Process Changes Presentation](#).

For application questions, contact the CIRM Review office at review@cirm.ca.gov.

To request a consultation, email clinical@cirm.ca.gov.