



FAQs on Clinical Program (CLIN 1 & CLIN2) Application Postponement

Why is CIRM postponing acceptance of new CLIN1 and CLIN2 applications?

As a leader in the regenerative medicine field, CIRM has experienced an unprecedented influx of clinical grant applications. This temporary postponement is due to the high influx of grant applications and is necessary to allow CIRM to carefully manage the flow of applications entering the system to ensure that quality of review is maintained and that the output aligns with our budgetary goals.

The increase in application submissions is placing a strain on CIRM resources and capabilities, including the Grants Working Group (GWG), which consists of scientific reviewers and the ICOC patient advocates. The CIRM review process for clinical stage applications cannot reasonably support monthly cycles that experience large volumes, while retaining the level of attention and rigor that we strive to maintain.

The amount of funds requested by all currently submitted clinical stage applications at various stages of the review process exceeds the amount of funds available in the 2023/2024 fiscal year budget. Based on the historical success rate of 50 to 60 percent, which includes applications that are resubmitted, currently submitted applications have the potential to deplete the remaining fiscal year budget and a continued influx of new applications would most likely increase that likelihood.

How long will this postponement last?

The temporary action and CIRM's progress towards addressing these issues will be re-evaluated at the June 2024 Board meeting.

Will this temporary action affect any applications that have been submitted?

This temporary action will not impact the review and approval of applications submitted on or before January 31st or the processing of any Tier 2 resubmissions.

Will this temporary action affect current CIRM awards?

This action will have no impact on the processing or management of approved grants. If you have any questions about your award, please contact your Science Officer or Grants Management Officer.

Is there a cutoff date in February to submit a new application?

All new applications submitted after January 31 will be subject to the postponement.

Has CIRM planned for a potential overflow of CLIN1 and CLIN2 applications when the postponement is lifted?

The temporary action and CIRM's progress towards addressing these issues will be re-evaluated at the June 2024 Board meeting.

Should I be prepared to submit an application at the end of June?

The temporary action and CIRM's progress towards addressing these issues will be re-evaluated at the June 2024 Board meeting.

Has CIRM postponed programs in the past?

CIRM has always been committed to advancing our mission while ensuring the most effective use of resources. Over the years, CIRM has employed a range of strategies to adapt to changing circumstances and to continue operating at our optimal capacity. Our aim is always to support the regenerative medicine field effectively while responding to the dynamic environment in which we operate.

How much is left in the CIRM clinical budget for this fiscal year?

The amount of funds requested by all currently submitted clinical stage applications at various stages of the review process exceeds the amount of funds available in the 2023/2024 fiscal year budget. Based on the historical success rate of 50 to 60 percent, which includes applications that are resubmitted, currently submitted applications have the potential to deplete the remaining fiscal year budget.

How will this decision affect the recently approved CLIN4 program?

CIRM, per its commitment to its mission, will be introducing a new CLIN4 program grant application for advanced pipeline projects moving to biologics license applications (BLA) in agreement with the FDA.

How does this decision affect other funding programs at CIRM?

This action may result in minor delays in the review and launch of discovery and translational programs, and applicants will be informed.

How can applicants find out about the status of their application?

Applicants can reach out to the Review office at review@circm.ca.gov.