CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Memorandum

To: Members of the Independent Citizens' Oversight Committee
From: Ross Okamura, PhD, Fellow, Preclinical Development; Lisa McGinley, PhD, Senior Science Officer, Preclinical Development; Rosa Canet-Avilés, PhD, Chief Science Officer
Re: Amendments to PDEV and RAPID Concept Plans
Date: June 25, 2026

Executive Summary

The CIRM team proposes amendments to the Preclinical Development (PDEV) and Rare Disease Acceleration Platform and Innovation and Delivery (RAPID) program concept plans to incorporate two eligibility criteria:

1. The CIRM applicant would be required to serve as the IND sponsor for the proposed therapeutic(s)
2. Applicants would be required to incorporate at least one California clinical trial site, as appropriate to the stage and scope of the proposed activities.

These two criteria are aligned with existing requirements under the current Clinical Development (CLIN2) program and are intended to strengthen patient access, regulatory accountability, and programmatic consistency across CIRM's preclinical and clinical-stage funding programs. The CIRM team requests that the ICOC approve the amendments that have been recommended by the Science Subcommittee in their meeting on May 29, 2026.

I. Background

The board initially approved the Preclinical Development (PDEV) concept plan in March 2025 and approved an amendment in March 2026. The board approved the Rare Disease Acceleration Platform and Innovation and Delivery (RAPID) concept plan in January 2026. While implementing the programs, the CIRM team realized both concept plans would benefit from the addition of two eligibility criteria consistent with the already implemented Clinical (CLIN2) program. Eligibility criteria are conditions that must be met in order to be able to receive CIRM funds.

II. Proposal

The CIRM team proposes the addition of the following eligibility criteria to the PDEV and RAPID program concept plans:

1. CIRM applicants must be the IND sponsor. The IND sponsor (i.e., the entity named as the sponsor on the IND) for the proposed therapeutic(s) must be the CIRM applicant organization (if an organization-sponsored IND) or the CIRM PI (if an investigator-sponsored IND).
2. Applicants must incorporate at least one California clinical trial site, as appropriate to the stage and scope of the proposed activities. This includes consideration of California sites in clinical development planning activities, inclusion of a California site in clinical trial start-up activities (if proposed) and inclusion of at least one California site in clinical trial conduct as applicable (e.g. in RAPID Validation awards). Applicants must justify inclusion of any sites located outside California and are encouraged to use CIRM Alpha Clinic sites when feasible.

The proposed changes are supported by the following considerations:

- **Patient Access and State Benefit**: Requiring California clinical trial site inclusion helps ensure that California patients have meaningful access to CIRM-funded clinical trials and that state-funded research provides direct benefit to Californians.
- **Operational Oversight and Accountability**: Requiring the CIRM applicant to serve as the IND sponsor ensures appropriate oversight, accountability, and alignment between the funded entity and regulatory responsibility for the clinical program.
- **Programmatic Consistency**: Aligning these requirements across PDEV, RAPID and CLIN2 promotes consistency in program implementation, clarity for applicants, consistency in review and alignment with CIRM's broader clinical development framework.

The criteria are consistent with established requirements in the CLIN2 program and reflect standard expectations for clinical development funding within CIRM.

III. Science Subcommittee Discussion

During the Science Subcommittee meeting held on May 29, 2026, the discussion with the Science Subcommittee members focused primarily on the IND sponsor requirement. One subcommittee member questioned whether requiring the funded applicant and IND holder to be the same entity could create unnecessary burden, noting that IND sponsors and clinical investigators are not always the same in clinical research. CIRM staff explained that the proposed requirement was intended to strengthen operational oversight,

accountability, and alignment between the funded organization and the entity holding regulatory responsibility for the program. Staff also noted that the amendments would promote consistency across CIRM's development-stage funding programs, while the California site requirement would further support patient access and state benefit objectives. Following the discussion, the motion to recommend the amendments to the full Board carried.

IV. Summary of Requested Action

The CIRM team requests that the ICOC approve the two additional eligibility criteria for PDEV and RAPID concept plans.

V. Exhibit(s) to Memo

- PDEV Concept Plan – Tracked Changes – 15JUNE2026
- RAPID Concept Plan – Tracked Changes – 15JUNE2026