Good afternoon. My name is Julia Carnevale, and I'm here on behalf of a multi-institutional team: myself, Alex Marson, Brian Shy, and Justin Eyquem at UCSF; Scott Nowicki and Antoni Ribas at UCLA; Shengdar Tsai at St. Jude; and Daniela Bircoff at Indiana University. We have spent over three years, with weekly meetings, developing what we believe is a transformative approach to cell therapy for solid tumors.

Here is the problem: Many groups, including ours, have identified dozens of promising genetic modifications that could make T cell therapies work better against solid tumors. But the path from CRISPR screen to clinical trial is painfully slow, with each edit needing to be tested one at a time, in separate trials that often are not comparable. At this pace, testing each modification individually would take decades. Patients with aggressive cancers don't have that kind of time.

Our solution is a clinical trial that tests 50 of the most promising gene edits simultaneously, in parallel, within a single patient's T cell product. We selected a T cell receptor with a long track record of safety and efficacy, based on Drs. Ribas and Nowicki's clinical experience in a prior CIRM-funded trial. Within the product, a small subset of cells would contain pooled, traceable gene edits. After treatment, we collect blood and tumor biopsies to assess which edits enabled T cells to best survive and infiltrate tumors—linking those edits to the most effective T cell states using single-cell analysis. Because each cancer is different, this platform allows us to identify optimal modifications for each disease context, rather than assuming one-size-fits-all.

This isn't theoretical. We have validated the approach preclinically. We had a successful INTERACT meeting with the FDA. We have been developing a clear regulatory path. We originally submitted this as a CLIN1 application; after the funding pause, we transitioned to a PDEV application.

We were surprised and disappointed to learn our application was not reviewed, on the basis that it did not meet enough of the stated preferences. The current triage rubric appears to systematically exclude innovative cancer cell therapy projects, and in fact, appears to exclude cancer therapy entirely. If that is the intent, it represents a significant departure from CIRM's prior funding priorities and a real loss for California cancer patients who are running out of options.

We respectfully ask the board to reconsider how these applications are triaged, and to ensure that transformative cancer cell therapy research has a path to scientific review.

Thank you.