Concept Proposal: Amendments to Special Call for Projects Related to COVID-19

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April 10, 2020

CIRM
CALIFORNIA'S STEM CELL AGENCY

Background

- Given the urgent need to develop treatments for COVID-19, the CIRM Governing Board approved the launching of a solicitation in support of promising discovery, translational, preclinical and clinical trial stage projects that could quickly advance treatments to patients in need.

- CIRM is utilizing its established partnering opportunities in Discovery (DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to facilitate the application, review and funding process.

- The Board approved an allocation of $5 million to support this new program.

Proposed Amendments to the COVID-19 Concept Plan:

- Increase scope to include investigational studies with convalescent plasma and its derivatives as a potential vital research opportunity
- Allow use of the FDA's single-patient emergency IND (eIND) pathway for clinical studies with convalescent plasma or derivatives.
- Allow funded clinical projects to start incurring allowable project costs from the date of the application submission deadline

Why convalescent plasma and its derivatives may offer a potential vital research opportunity

- Convalescent plasma is the component in blood collected from patients who have recovered from an infection that contains antibodies against the virus.
- Use of convalescent plasma as an investigational treatment for patients with COVID-19 has shown promise in the clinical setting but it is not yet an approved product.
- FDA is permitting the emergency investigational use of convalescent plasma to treat COVID-19 under the criteria of the emergency IND in addition to the standard IND mechanism.
- More clinical data collected from well-designed trials and studies are needed to determine if this approach could be used more broadly.

How CIRM is uniquely positioned to make an impact

- CIRM would only fund projects that use convalescent plasma as a treatment for COVID-19 patients in need (i.e., not prophylactic use).

- CIRM would support formal studies that collect clinical data for analysis to better assess the scientific and medical value of this therapeutic approach.

- CIRM can leverage infrastructure in California, such as established clinical networks to reach more patients and facilitate plasma collection.

For Board Action:
Determine if convalescent plasma and derivatives for treatment of COVID-19 should be eligible

- Convalescent plasma (and its derivatives) is a biologic that is not currently eligible for entry into CIRM funding opportunities
- Under Proposition 71, CIRM is permitted to fund projects that are not stem cell-related only if they are deemed a "vital research opportunity".

  "Vital research opportunity means scientific and medical research and technologies and/or any stem cell research not actually funded by the institute under subparagraph (C)…which provides a substantially superior research opportunity vital to advance medical science"
- If the Board determines that convalescent plasma projects are a potential "vital research opportunity," the COVID-19 program announcement would be amended to include convalescent plasma and its derivatives as eligible for funding. Those programs would undergo GWG review based on the "vital research opportunity" process used for gene therapy applications.

For Board Action:

Additional Amendments to the COVID-19 Concept

- Clinical studies of convalescent plasma may propose use of the FDA's single-patient emergency IND (eIND) pathway to satisfy the CLIN2 eligibility requirements for a traditional IND.

For Board Action:

Additional Amendments to the COVID-19 Concept

- Allow funded clinical programs (CLIN1 and CLIN2) to start incurring allowable project costs, at risk, from the date of the application submission deadline.