

SOMETHING BETTER THAN HOPE

Concept Proposal: Special Call for Projects Related to Covid-19

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Overall Concept

- Given the urgent need to develop treatments for COVID-19, CIRM proposes to launch a solicitation in support of promising discovery, translational, preclinical and clinical trial stage projects that could quickly advance treatments to patients in need.
- CIRM plans to utilize its established partnering opportunities in Discovery (DISC2), Translational (TRAN1), and Clinical (CLIN1,CLIN2) stages to facilitate the application, review and funding process.
- CIRM requests an allocation of \$5 million to support this new program.
- CIRM will create an expedited process for application and review.

Program Announcement Changes

Open the DISC2, TRAN1, CLIN1, and CLIN2 program announcements with the following award limitations:

Project Stage	Specific Program	Award Amount*	Award Duration
Clinical trial	CLIN2	\$750,000	24 months
Late stage preclinical	CLIN1	\$400,000	12 months
Translational	TRAN1	\$350,000	12 months
Discovery	DISC2	\$150,000	12 months

*Award limits are for Total Funds Requested (i.e., limit includes direct facilities costs and indirect costs)

Program Announcement Changes

- Only projects pursuing the development or testing of a candidate for COVID-19 will be considered.
- The applicant must be ready to initiate work on the funded project within 30 days of approval.
- Small molecule or biologic (e.g., monoclonal antibodies) candidates are eligible for all programs and clinical trial phases if they meet the following criteria:

A small molecule or biologic that acts on or is dependent on endogenous stem cells for its therapeutic effect, that modifies a stem cell product, OR where a stem cell is necessary to manufacture the therapy.

- Manufacturing of product to supply a follow-on clinical trial will not be allowed.

Program Announcement Changes

- All projects must propose to achieve a clear deliverable within six months of project initiation to demonstrate progress toward the goal.
 - For clinical trial projects (CLIN2), applicants must propose to initiate enrollment and collect data within 6 months from the project start date.
 - For late stage preclinical projects (CLIN1), the proposed date of IND filing must be within 6 months from the project start date.
 - For translational projects (TRAN1), the proposed date of Pre-IND meeting or equivalent interaction with the FDA must be within 6 months from the project start date.
 - For discovery projects (DISC2), applicants must propose to have data for a viable candidate that has a likelihood of progressing quickly to the clinic.
- Proposals for development or clinical testing of a device or tool candidate will not be supported, except under the DISC2 opportunity.

Proposed Change to GWG Scoring

In order to align the scoring of all applications, we propose to apply the current scoring method used for non-clinical programs to the clinical programs as well. The method uses a scale of 1-100 with the median score of all scientific members determining the funding recommendation.

1. Recommended for Funding = median score 85 and above, representing applications that have exceptional merit and that warrant funding, if funds are available; or
2. Not Recommended for Funding = median score below 85, representing applications that are not recommended for funding.

Current Research Budget Allocation

Program	Allocation	Commitments	Remaining
CLIN Cure Sickle Cell	\$30,000,000	\$2,242,805	\$27,757,195
Progression Awards	\$1,840,000	\$237,060*	\$1,602,940
Conference Award	\$250,000	\$0**	\$250,000
Total	\$32,090,000	\$2,479,865	\$29,610,135

*2 applications under review, estimated total \$460,000

**RFA open for applications due 4/10/2020

Unallocated Recovered Funds (as of 3/25/2020)	\$812,042
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Allocation for Consideration

Program	Proposed Allocation
COVID-19	\$5,000,000

Budget request to make \$5 million available for COVID-19 projects:

1. Allocate \$812,042 of current unallocated recovered funds
2. Borrow \$4,187,958 from CLIN Cure SCD with future recovered funds first used to fully replenish this amount

COVID-19 Concept Request

CIRM requests approval for the following:

- Allocate \$5 million to a COVID-19 funding opportunity
- Approve opening of the DISC2, TRAN1, CLIN1, and CLIN2 funding opportunities and modification of the respective program announcements for COVID-19 projects
- Approve use of the non-clinical application scoring method by GWG for all applications related to COVID-19, including CLIN1 and CLIN2

Revised Research Budget

(pending ICOC approval)

Program	Revised Research Budget
CLIN Cure SCD	\$23,569,237
Progression Awards	\$1,602,940
Conference Award	\$250,000
Unallocated Recovered Funds	\$0
COVID-19	\$5,000,000
Total Research Budget	\$30,422,177