

SOMETHING BETTER THAN HOPE

Concept Proposal for Alpha Stem Cell Clinics Supplement

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CIRM Alpha Stem Cell Clinics Network



- \$40 million investment in patient-centered care and training
- Successfully accelerating cell and gene-therapy clinical trials
- Over 105 trials supported since 2015
 - 82 from industry sponsors
 - 23 CIRM-funded industry and academic sponsors
- Over \$57 million in industry-contracts

*presented at January ICOC meeting

Alpha Stem Cell Clinics portfolio

Current Status & Challenge

- All 5 of the existing Alpha Clinic awards have ended or are approaching the end of their award period
- New Concept Proposal for Alpha Clinics Expansion to be brought to ICOC with Strategic Plan rollout and targeted program launch in 2022
- Alpha Clinics Directors have reported that bridge funding is needed to support critical personnel and continued operations as a network during this period

Alpha Stem Cell Clinics portfolio data

Awardee	Start Date	End Date	Total Award Amount	Award Status	Potential Gap (months)
City of Hope	02/01/15	7/31/20	\$8M	Closed	22
UCLA	04/01/15	3/31/21	\$8M	Closed	14
UCSD	02/01/15	7/31/21	\$7.99M	Active	10
UC Davis	12/01/17	11/30/21	\$7.91M	Active	6-12*
UCSF	12/01/17	11/30/21	\$7.99M	Active	6-12*
*Projected to achieve the final milestone early. Target is May 2021					

Proposal for continued funding

Supplement Proposal

- Provide a 1-year supplement from June 2021 to May 2022 when a new RFA would be launched.
- This supplement would support talent retention & program activities that are specified in the original RFA which includes:
 - Coordination of clinical research & manufacturing teams consistent with protocol needs
 - Regulatory support of ASCC Clinical Operations Management & Senior CRCs
 - Product processing
 - Bio-specimen collection & coordination for correlative studies
 - Management of patient & public inquiries to the Alpha Clinics
 - Fees for service contracting

Proposal for continued funding

Supplement Allocation

- Average annual expenditures per award (includes direct project costs & facilities costs) is \$1.36M
- Total supplement award is \$680,000 with a 1:1 Awardee matching requirement.
- Awardees will be required to submit a justification for funding with a detailed budget for critical activities to maintain key personnel & continue operations
- Awardees with project periods less than 12 months will be required to reduce project budgets in proportion (\$57,000 per month based on the average expenditure burn rate)
- CIRM proposes a total allocation of \$3.4M for 5 supplement awards

Summary of Supplement Budget

	Alpha Clinics
Average annual expenditures per award (direct costs & average facilities rates)	\$1.36M
Total Supplement per Awardee	\$680,000
# of awards eligible for supplement	5
Proposed Allocation	\$3.4M

Requested Action

CIRM requests the Science Subcommittee recommend this proposal to the ICOC for an Alpha Clinics Supplement with an allocation of \$3.4M