

Accelerating Center (AC) FAQ's

Revised March 28, 2016

- Q: Do the AC core services include monitoring clinical trials for the Alpha Clinics?
 - A: Yes, monitoring clinical trials is within the scope of services provided. Services will be scaled based on the needs of the sponsor – some sponsors will rely on the Alpha Clinics site and the AC, while others bring in their own CRO's to support the trial outside of the Alpha Clinics Network.
- Q: Are the trial sponsors mainly academic investigators / physicians or industry sponsors?
 - A: A list of the current Alpha Clinic trials may be found here: <https://www.cirm.ca.gov/patients/alpha-clinics-network/alpha-clinics-trials>. The AC will support trials on behalf of both academic investigators and industry sponsors.
- Q: Does CIRM hold the INDs for the trials conducted by the AC?
 - A: No. The INDs are held by the trial sponsors. Trial sponsors will include investigator and industry sponsored trials.
- Q: Is the AC required to conduct 50 clinical trials as outlined in CIRM's Strategic Plan?
 - A: No.
- Q: Will the AC have to bid on CIRM-sponsored projects?
 - Yes. CIRM-sponsored projects will not be required to use the AC. The AC will need to offer a competitive rate.
- Q: Is the \$15 million Accelerating Center award the sole source of funds available to support CIRM-funded projects.
 - A: The \$15M is to fund personnel and operations and a portion of the \$15M can be used to offset the reduced rate the AC may offer to CIRM funded projects. Note: The Accelerating Center will contract directly with each of the Sponsors.
- Q: Will the AC mainly be focused on clinical trials or preclinical studies?
 - A: The activities to be performed under this award are primarily focused on clinical trial support. In the future, the AC will work with the CIRM Translating Center (and the FDA) on filing IND's for preclinical stage programs. A primary responsibility of the AC, for preclinical studies, is the development and coordination of a regulatory strategy to ensure a successful IND filing.
- Q: What are the requirements for California operations and can work be performed outside CA?
 - Applicants must conduct a majority of the Accelerating Center's operations from a facility located within California that is equipped to provide the required core services. The Center Director and a majority of the Center's dedicated staff must work out of the California facility and any effort for which salary is claimed must be expended in California. The Center Director must commit 100 percent effort to the Center for the first three years of CIRM-funding and no less than 80 percent effort thereafter for the duration of the award.
 - Awardees may use CIRM funds for Allowable Project Activities conducted both in California and outside of California. "Allowable Project Activities" means those activities that are conducted in California and those activities conducted outside of California, provided that: (a) the Awardee exercises direction, supervision and control over the activities and (b) if a separate out-of-state organization performs project activities, that

organization does not retain intellectual property or publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.

- Q: Is the RFA focused on a single source CRO?
 - A: No, a CRO with specialized services may apply assuming they meet the requirements outlined in the RFA. A specialized CRO may also partner with other organizations to provide a competitive proposal.
- Q: Does CIRM own any of the IP of the sponsors that will be conducting the trials?
 - A: No, CIRM does not own any IP. All of the IP resides at the entity or institute which receives our funding.
- Q: Can the AC work with non CIRM-funded trials, or is the AC limited to working only with CIRM-funded trials?
 - A: The AC may not use CIRM funds to subsidize the direct costs of services provided to non-CIRM funded projects. However, the Accelerating Center may charge commercially reasonable fees to support other non-CIRM funded projects. As part of the AC's overall and long-term sustainability, the AC is encouraged to work with non CIRM-funded trials in addition CIRM-funded trials.
- Q: Can the AC subcontract services to a third party? If so, can these services be subcontracted outside of CA?
 - A. Yes, the AC can subcontract services to other entities, including the Alpha Stem Cell Clinics, as they deem appropriate. Yes, these services can take place outside of CA.
- Q: Will there be an in-person 'pitch' component to the application process?
 - A: Yes. Eligible applicants will have the opportunity to make an oral presentation at the time of application review. Presentation guidelines will be provided to eligible applicants after receipt of a completed application.
- Q: What CIRM polices / regulations apply to this grant.
 - CIRM policies are described in its Grants Administration Policy (GAP). The Clinical GAP broadly represents the terms and conditions of the Award:
https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf
 - However, there are specific sections that are not applicable to the Accelerating Center award, including (1) Application Tiered Scoring and the (2) Loan Conversion.
- If we propose to utilize company employees outside CA to support our operations and we are not creating contracts for this work, are we required to identify these employees as consultants? The Consultants / Subcontracts / Service Contracts grant section requires us to list the use of consultants.
 - Consultants are external to the parent organization. Employees from your organization supporting the award outside CA can be identified as organizational assets.
- When the Alpha Network Sites are at capacity, are they required to provide priority services to CIRM grantees?
 - The Alpha Clinics are expected to maintain a high standard of care that is applied to any trial in the Network regardless of sponsor / funding organization. CIRM does not require the Alpha Clinics to prioritize CIRM grants.
- Are there any restrictions on compensation for AC employees in CA?
 - The maximum salary (including bonuses) that can be charged to the CIRM award for a 100% effort is \$230k per year. See

https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf

In addition, fringe benefits can be charged to the CIRM award in proportion to the salary requested.

- Are there any restrictions on how grant funds can be used (e.g. travel)? Is there a list of approved / non-approved uses?
 - Please reference the CIRM Grants Administration Policy

https://www.cirm.ca.gov/sites/default/files/files/funding_page/Policy_Incorporated_by_100503_010616.pdf

- In the Business Plan and Sustainability section, there are two questions regarding sustainability – (1) *Describe how the Accelerating Center will provide services based on the requirements set forth in this RFA and build a business sustainable beyond the five-year award period and (2) Describe how the Accelerating Center will remain sustainable after the award period?* How do these questions differ?
 - For question (1) discuss how performing the CIRM-funded activities over the 5-year award period will position the Center for sustainability.
 - For question (2) Describe how expansion of services or provision of additional services beyond that supported by CIRM funding will contribute to a sustainable future business.