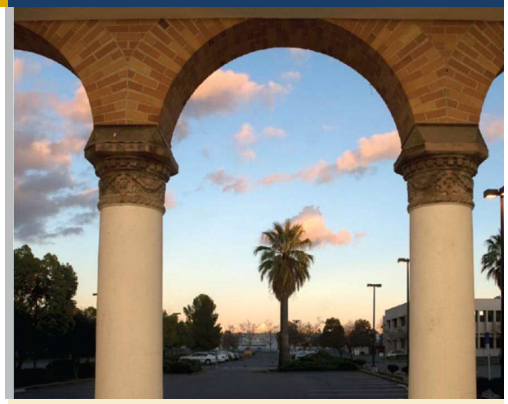
UC DAVIS HEALTH

Offerings to the Alpha Clinics Network

Regulatory and Grant Consultation



UC Davis Health Alpha Clinic

Member of

CIRM ALPHA CLINICS NETWORK

Regulatory Services

On a case-by-case basis, the Institute for Regenerative Cures partners with teams of investigators to provide regulatory assistance customized to the particular needs of individual projects, including:

- Regulatory consultation for the development of biologic and combination products in the translational phase
- Assistance with the development of numerous types of U.S. Food and Drug Administration (FDA) meeting requests and information packages as well as post-meeting evaluation of FDA comments
- Preparation and submission of IND applications to the FDA, including coordination of responses to comments during the review process

Contact:
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Grant Preparation and Submissions

On a case-by-case basis, the Institute for Regenerative Cures partners with teams of investigators to assist with the development of grant applications to funding agencies; including NIH, CIRM, and various foundations.

UC Davis Alpha Clinic (UCDAC) Grant Consultation services include:

- Providing strategic feedback on drafts of major grant application components
- Editing services on drafts of major grant application components
- Performing due diligence on CIRM's Access & Affordability requirements
- Drafting CIRM's Access & Affordability requirements

Contact:
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Experience Beyond the Bench

Institute staff have exceptional skills and experience with cell and gene therapy and gene-modified adult stem cells and their translation from pre-clinical phases to clinical investigations. Hourly consultation rates are available.