UCLA | OFFICE OF CLINICAL RESEARCH
CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE

CIRM ALPHA CLINICS NETWORK

FDA Regulatory Support Consultation Services for the California Institute for Regenerative Medicine (CIRM) Alpha Clinics Network

The **UCLA FDA Affairs Team** plays a vital role in guiding research projects, clinical trials, and new medical technologies through the complex regulatory landscape required to achieve FDA approval or clearance. We have extensive experience with cutting-edge cell and gene therapies and regenerative medicine trials. Our team ensures compliance with applicable regulations, facilitates communication with regulatory bodies like the FDA, and supports the translation of innovative research into approved medical products or therapies.

Our main tasks include, but are not limited to:

- **Regulatory Strategy Development**
- **FDA Submissions Management**
- **FDA Liaison and Communications**
- **Regulatory Education and Training**

KEY SERVICES PROVIDED

Product Classification and Regulatory Pathway Evaluation
Determine product classification (e.g., drug, device, combination product, biologic) and assess the need for an Investigational New Drug (IND) or Investigational Device Exemption (IDE)

IND/IDE Application Support
Assist with IND or IDE applications and subsequent submissions, including pre-submissions (e.g., INTERACT, pre-IND/IDE meetings), amendments, safety/annual/final reports, and special designations such as Orphan Drug Designation (ODD), Regenerative Medicine Advanced Therapy (RMAT)

Protocol Development
Clinical protocol development in support of FDA submissions

FDA Meeting Support
Preparation, coordination, and attendance at FDA meetings including pre- and post-meeting documentation and correspondence with the FDA and research team

FDA Inspection Support
Preparation for and regulatory support during FDA inspections of investigator-sponsored clinical trials

Regulatory Consultation & Education
Provide consultation and presentations to investigators, study teams and community regarding drug, device, and biologic products and technology

ResearchGo
UCLA ResearchGo is an online portal of tools, templates, guidance, go-to, and resources for investigators, study staff, and partners/affiliates.

To discuss how we can provide services for your CIRM Alpha Clinic Network trials, please contact us at FDAConsults@mednet.ucla.edu

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