Contract Research Organization (CRO) Services for the California Institute for Regenerative Medicine (CIRM) Alpha Clinics Network

Since 2010, Cedars-Sinai's Office of Research Compliance and Quality Improvement (ORCQI) has offered clinical trial monitoring services as part of the Post-Approval Monitoring and Research Compliance (PAM) team. To date, we've monitored over 30 trials where Cedars-Sinai was a clinical site. The PAM team is made up of three certified clinical research professionals (CCRPs) with 15 years combined experience monitoring clinical research. Our academic mission enables us to offer quality assurance (QA) monitoring services at an affordable cost.

QA Monitoring Services

Focus on Good Clinical Practices (GCP) compliance:

- Site Initiation Visits (SIVs)
- Interim Monitoring Visits (IMVs)
- Close Out Visits (COVs)
- Site FDA inspection preparation

Process

1. Discuss trial-specific QA monitoring plans and contracting
2. Initiate QA monitoring services
    a. Ensure electronic data capture systems are validated against protocol objectives
    b. Review subject and regulatory records
    c. Review and prompt safety reporting
    d. Verify eCRF data entered in the database against source documentation
    e. Review investigational drug service records
    f. Ensure regulatory compliance, including FDA Part 11 and clinicaltrials.gov
3. Collaborate and communicate with sponsor and trial sites through closure

Contact **groupIRBcompliance@cshs.org** to discuss how we can provide QA monitoring services for your CIRM Alpha Network trials.