City of Hope
CANCER CENTER

CIRM ALPHA CLINICS NETWORK

Regulatory Affairs Support
for the CIRM Alpha Clinics Network

The **City of Hope Office of IND Development and Regulatory Affairs** has extensive experience and a strong track record with IND submissions for cellular and gene therapy, biologics and small molecule products for early phase clinical trials. The team provides regulatory strategy, planning, and application preparation, as well as manages and coordinates engagement with regulatory agencies for both internal programs and external collaborators, including academic institutions and biotechnology companies.

Regulatory Affairs Support

- Gap analysis and risk assessment of investigational drug development plans, with a focus on regulatory strategy to address potential regulatory health authority concerns
- Guidance and preparation for health authority interactions (INTERACT, pre-IND, end of phase meetings)
- Regulatory document authoring, including meeting requests and packages, IND modules, investigator's brochure, study reports and other supporting documents
- Submissions planning and support
- Lifecycle management to ensure compliance of regulatory applications

To discuss how we can provide services for your CIRM Alpha Clinic Network trials, please contact Catherine Cortez at **cacortez@coh.org**