



*Visionary science for
life changing cures.*

Clinical Research Associate

Applied Genetic Technologies Corporation (AGTC) is a clinical stage biotechnology company dedicated to developing novel gene therapies for ophthalmic diseases. AGTC is aggressively expanding and seeks a full-time Clinical Research Associate

Reporting Relationship:

- The Clinical Research Associate will report directly to the Clinical Trial Manager.

Responsibilities:

Job responsibilities will include, but are not limited to, the following.

- Ensure that site qualification (pre-study), initiation, monitoring and study closeout visits are conducted in accordance with AGTC SOPs, GCP and ICH Good Clinical Practice guidelines, and federal regulations
- Perform monitoring activities of assigned sites and be primary liaison for all clinical monitoring issues, escalating as appropriate to Clinical Trial Manager in accordance with relevant study plans and Standard Operating Procedures.
- Be accountable for the coordination of monitoring activities, ensuring appropriate CRA visit scheduling per protocol and monitoring plan with reporting on monitoring activity to include status report, co-monitoring visits and trip report metrics.
- Manage study sites to ensure enrollment goals are met in accordance with study timelines
- Assist in IRB submissions and communications throughout the study duration
- Responsible for collaborating with sites and CRAs (if applicable) to develop any Corrective and Preventative Action Plan (CAPA) relating to non-compliance at sites.
- Responsible for attending, participating and presenting at Investigator meetings as needed
- Assisting with project specific training, oversight and mentoring of contract and/or CRO CRAs
- Supporting the Clinical Research Manager in communicating and resolving issues and obtaining follow-up information
- Participate in the development and preparation of study documents such as Monitoring plan, Manual of Procedures, Protocol, Case Report Forms, Informed Consent, etc.

Requirements:

The successful candidate will meet the following requirements.

- B.S. in a scientific discipline and at least five (5) years' experience working in clinical research environment that includes clinical trial monitoring and hands-on site clinical trials management.
- Experience working with biotechnology products preferred and previous experience in ophthalmology clinical trials would be advantageous.
- Knowledge of GCP guidelines and clinical trial processes required

AGTC offers competitive compensation commensurate with education and experience. AGTC is an EOE and maintains a drug-free workplace. Please send CV or resume to:

Human Resources
Applied Genetic Technologies Corporation
14193 NW 119th Terrace, Suite #10
Alachua, FL 32615
jobs@agtc.com

14193 NW 119th Terrace, Suite #10, Alachua, FL 32615 • 386.462.2204 • agtc.com