



*Visionary science for
life changing cures.*

Clinical Data Manager

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 Data Manager.

Reporting Relationship:

- The Clinical Data Manager will report directly to the Clinical Research Manager

Responsibilities:

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

- Provide oversight of clinical data management activities across one or more early-stage studies
- Direct the development and maintenance of Case Report Forms (CRFs), CRF Completion guidelines, edit check specifications, data transfer specifications, and database audit plans
- Hands-on oversight of the build, development and maintenance of the Electronic Data Capture (EDC) systems and the integration of IxRS (if applicable)
- Perform and organize cross-functional User Acceptance Testing of integrated clinical databases
- Contribute to the design and development of study documents including Clinical Protocol, CRFs, and Statistical Analysis Plan (SAP)
- Direct the interaction with contract data management groups to ensure that data management tasks remain on target per project timelines
- Proactively organize on-going data review throughout the conduct of the study to ensure timely and appropriate identification of errors, trends, and discrepancies by working with a contract data management group and internal stakeholders
- Responsible for the correction of errors and discrepancies through the site query process, for documenting permanent data issues, routinely communicating issues with team members, and the delivery of a quality locked database for analysis
- Provide input to complex problems in which analysis of situations or data requires an in-depth evaluation of various factors

Requirements:

The successful candidate will meet the following requirements.

- Bachelor's degree in clinical, biological, mathematical sciences or related field or equivalent experience required; advanced degree is a plus; with at least 5 years of clinical data management experience in biotechnology or pharmaceutical industry with outsourced CRO oversight experience; previous ophthalmology experience preferred
- Strong understanding of and experience with CDISC standards, including experience with SDTM and AdAM datasets

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
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