



Job title	<i>Senior Clinical Trial Manager</i>
Reports to	<i>Vice President, Clinical Operations</i>

Company

Actinium Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing radiopharmaceutical therapeutics for the treatment of disease, particularly cancer. Our Antibody Radiation-Conjugates (ARCs) combine the tumor targeting ability of antibodies with the cell killing ability of radiation. Notably, Actinium possesses proprietary expertise and know-how for the development of novel ARCs armed with the potent alpha emitting radionuclide warhead Actinium-225 (^{225}Ac). With our technology and our development capabilities, we are advancing a multi-disease, multi-target pipeline of preclinical and clinical-stage ARCs for targeted conditioning and as therapeutics for the treatment of hematologic malignancies and solid tumors. Building on our expertise and leadership in radiopharmaceuticals, Actinium is rapidly accelerating our investigational research efforts and is looking for talented scientists to join the team.

Job Overview

The ideal candidate is a college graduate with strong background in science and prior experience working on clinical trials. Candidate must be an experienced team player with strong communication and interpersonal skills, with interests in clinical trial management. Prior experience in radiopharmaceuticals/oncology strongly preferred.

JOB DESCRIPTION:

- Oversight and management of clinical trials with emphasis on interactions with investigators, study coordinators, and data managers at investigational sites; identification of potential recruitment issues, and preparation and review of all trial-related documentation (including clinical protocols, Investigator Brochures, Informed Consent Forms, etc.). Works closely and directly with cross-functional staff including drug-supply, regulatory, data management, safety and QA. Special focus working with and directing Clinical Research Associates and Site Coordinators.
- Organize and conduct training for internal team, site personnel and vendors.

- Conduct start-up activities including site qualification, budget negotiation, site initiation meetings in collaboration with a Contract Research Organization.
- Oversee and track trial-related activities (i.e., screening and enrollment metrics, data entry and quality, monitoring plans, collection of laboratory samples).
- Ensure regulatory compliance for trial conduct
- Track and ensure appropriate trial specific materials.
- Organize, participate in and document conference calls and meetings to review trial progress.
- Continuously track and check eCRFs. Ensure that data queries are responded to in a timely fashion.
- Ensure proper collection, tracking and review of SAEs. Confirm compliance with all regulatory requirements.
- Maintain all trial related documentation including: IRB approvals; CVs of investigators and study personnel; clinical IB; protocols; instructions and training material; ICFs; CTM shipping orders; start-up meeting attendance documentation; letters of agreement; all investigator and site correspondence.
- Participate in clinical departmental planning sessions, and SOP development.
- Maintain close interaction with the CRO involved in the study, and work with the clinical research assistants from the CROs to ensure that their role and contribution is optimized.

Requirements

- Bachelor's degree or higher required (science-related degree required)
- Sr. CTM candidates should have at least 6 years of relevant clinical trial experience
- Excellent knowledge of medical terminology and familiarity with clinical trial process required
- Strong ICH-Good Clinical Practice knowledge
- Experience using computerized information systems, electronic spreadsheets, word processing and electronic mail
- Ability to travel an estimated 10% on average

Compensation will be commensurate with experience. Actinium offers competitive base salaries, performance bonuses, equity incentive plans, 401(K) with company matching and comprehensive health benefits.