POSITION PROFILE:

Senior Clinical Trial Manager

Acer Therapeutics Inc.
(Nasdaq: ACER)
www.acertx.com

June 2021

Company Overview

We are a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs. Acer was founded in 2013, went public in 2017 and raised $100 million to date. Acer's pipeline includes four programs: ACER-001 (sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); EDSIVO™ (celiprolol) for the treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; ACER-801 (osanetant) for the treatment of induced Vasomotor Symptoms (iVMS); and ACER-2820 (emetine), a host-directed therapy against a variety of infectious diseases, including COVID-19. Each of Acer's product candidates is believed to present a comparatively de-risked profile, having one or more of a favorable safety profile, clinical proof-of-concept data, mechanistic differentiation and/or accelerated paths for development through specific programs and procedures established by the FDA.

The company is led by a management team experienced in the development and commercialization of rare disease therapeutics. Acer's strategy is predicated upon time and cost-efficient drug development, with the goal of delivering safe and effective therapies to patients with the utmost urgency.

Acer has a strong company culture and is committed to creating and maintaining an environment that values individual rights, hard work, fosters creativity, and promotes success. The Company is growing and is fueled by the talent and expertise of our employees and driven by the commitment to treating patients with significant unmet medical needs.

Location – United States

As a part of the Acer team, you will have the opportunity to work where you're most productive. We have offices in Newton, Massachusetts and Bend, Oregon. Some travel, post COVID-19 pandemic, to our East Coast (Newton, MA) and West Coast (Bend, OR) offices may be required, as well as other US meeting locations.

However, most of us work out of a home office, co-working space, in a rainforest, at the beach, on a train, in a plane, you name it, we're there. We're a talented, unconventional and collaborative team that knows no boundaries who are always looking to work smarter and support one another. In addition to ultimate work flexibility, we also provide world-class benefits to support the ongoing health and wellness of our employees and their families.

Reporting Relationship

The Senior Clinical Trial Manager will initially report directly to the Vice President of Clinical Operations.

Job description
Acer is seeking a Senior Clinical Trial Manager. The role will serve as a key member of the clinical operations team and will also be expected to actively participate in planning and presentations to the executive committee. They will provide general management of clinical trials. The requirements for the position include significant experience in biopharmaceutical drug development.

This person will partner with their colleagues in Clinical Development, Clinical Operations as well as with multiple other internal teams including Medical Affairs, Regulatory, Safety, Program Management, and external CROs and medical monitors, to ensure the success of the clinical development programs.

Responsibilities

- Assist with developing clinical study protocols, case report forms and other tools to track clinical data.
- Assess adequacy of potential clinical investigators and sites, including evaluating facilities, personnel, patient referral base and adherence to Good Clinical Practices (GCPs).
- Act as a primary contact between Acer and multiple clinical sites; maintain close contact with sites via telephone, correspondence and visits.
- Instruct investigators and their personnel in regard to study protocol and regulatory requirements.
- Arrange for the availability of adequate study supplies.
- Travel to clinical sites to monitor compliance with study protocol, clinical trial material storage and accountability, GCP and FDA regulations, and overall clinical objectives. Verify accuracy of clinical data through comparison of case report forms to patient records at the sites.
- Write project updates, as needed, and coordinate project meetings, information and timelines to assure deadlines are achieved.
- Manage outside resources and vendors. Establish new vendor networks and manage new and already established vendor relationships.
- Assist in preparation for regulatory audits.
- Coordinate activities of associates and investigators to ensure compliance with protocol and overall clinical objectives.
- Additional study level activities include supporting presentations of study results to internal and external committees or advisory boards.

Success Factors

- Ability to work collaboratively and effectively with others
- Ability to work under pressure and meet deadlines
- Strong analytical and communication skills
- Well organized and detail oriented
- Proven ability to lead a cross-functional, matrixed team

- Strong communication and presentation skills
- Experience in a global organization
- Experience developing and managing budgets
- Excellent organizational skills, and the ability to apply extreme attention to detail and organization in all aspects of work
- Flexibility and an “all hand-on deck” approach

Qualifications

- 10+ years of industry experience
- B.S. or advanced degree, with proven biopharmaceutical clinical development experience in preferably both early and mid-late stage therapeutic programs. A record of accomplishment including developing, planning, designing, and executing clinical studies leading to the successful registration of therapeutics.
- Experience in regulatory submissions to the FDA and other regulatory agencies.
- Excellent writing and communication skills
- Ability to develop strong positive relationships with both internal and external stakeholders.
- Experience presenting to a wide variety of audiences including internal teams and the medical/scientific community.
- Ability to travel both domestically and internationally as needed
- Finally, the candidate will need to embrace Acer’s mission and core values.

Compensation

Acer seeks an individual of exceptional ability and will offer a competitive compensation package commensurate with candidate’s individual skills and experience.

Acer’s Mission

We founded Acer on the fundamental mission that we will invest in developing innovative therapies for people impacted by serious rare diseases with significant unmet medical need and make them broadly accessible. In an era when the pharmaceutical industry is making huge strides in advancing therapeutic options for rare conditions, that may not sound atypical. But we believe we have a better way and it will deliver significant value to patients and their caregivers, healthcare systems and society.

Be led by patients, their caregivers and clinicians.

We don’t just put patients first, we are fueled by their resilience to adversity. That’s why patients and their caregivers lead us in how to think about shaping our drug development programs so that our products will deliver optimal outcomes and earn the commitment of treating clinicians.

We recognize that drugs can offer tremendous benefit to patients and clinicians alike, but often leave both with an incomplete promise. That’s why we engage with patient and clinician communities in our targeted pipeline areas and listen to their needs in order to reflect their inputs early and throughout our

drug program development.

Indeed, such collaboration enables us to solve challenges and design solutions together.

Our Core Principles

1. Obligation to prioritize the Patient & their Family
2. Be Compassionate
3. Respect other's perspectives
4. Responsibility to do what's right – always!
5. Total Transparency
6. Celebrate Diversity
7. Humility
8. Be Courageous
9. Accountability
10. Be Unconventional

We will be accountable to this Ethos and Core Principles. We encourage open and transparent communication that can help us to drive our mission forward. We may seem impatient, but it is only because we want to get there faster. We are in this, together.

Acer is committed to continuously work to create a diverse and inclusive workplace and is proud to be an equal opportunity employer. Our goal is to promote a culture where diversity of thought, backgrounds, gender, gender identity, race, national origin, sexual orientation, religion, genetics, disability age or veteran status, is given equal consideration for employment.