



POSITION PROFILE:

Senior/Executive Director, Clinical Operations

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

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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 treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and Maple Syrup Urine Disease (MSUD); ACER-801 (osanetant) for treatment of induced Vasomotor Symptoms (iVMS); EDSIVO™ (celiprolol) for treatment of vascular Ehlers-Danlos syndrome (vEDS) in patients with a confirmed type III collagen (COL3A1) mutation; 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. In March 2021, Acer entered into a Collaboration and License Agreement with Relief for development and commercialization of ACER-001.

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 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/Executive Director Clinical Operations will report directly to the Group Vice President, Clinical Development.

Job Description

The role is responsible for all functional activities related to execution of Clinical Trials. The incumbent will lead and oversee a team of internal and external clinical project managers/specialists to meet individual clinical trial objectives and corporate goals as well as providing operational expertise to project teams



Job Responsibilities

- Directs, supervises and manages all aspects of clinical trials to ensure that corporate and department goals/objectives for clinical development programs are met on time and within budget
- Interacts with multidisciplinary teams in a matrix environment, developing resourcing, budgeting, financial and strategic planning for clinical programs/studies
- Create and execute clinical operational strategic plans in line with product strategy and resource allocation
- Responsible for strategy and clinical operation sections of regulatory documents including data summarization, protocols, Investigator Brochures, IND annual reports, and others as needed or requested
- Prepare and present clinical development trial updates to senior management, review any potential issues and propose any mitigations/recommendations
- Develop study feasibility, cost estimates, input into contracts, work/change orders and analyze tools and processes to support outsourcing efforts
- Build, develop and train staff, structure department for enhancing efficiency, and create a highly engaged work environment for attracting and retaining highly qualified clinical operations professionals
- Develop and ensure compliance with SOPs and guidelines, FDA regulations and current ICH GCP guidelines
- Oversee and maintain the relationships with Contract Research Organizations, investigative sites and KOL's
- Participate on project teams and study teams as needed or requested
- Maintain a high level of professional expertise through familiarity of clinical literature, knowledge of therapeutic area, current medical practice and pharmaceutical regulations

Job Requirements

- Minimum B.S. degree, PhD or PharmD preferred, with a minimum of 10 years clinical research experience in the pharmaceutical/biotechnology industry, with at least 8+ years managing clinical programs with experience managing staff pertaining to the management of clinical programs.
- Thorough knowledge of the clinical research process, FDA, EMA and other regulatory requirements that may impact global clinical studies as well as ICH and GCP guidelines.
- Demonstrated success identifying, negotiating and overseeing outsourced clinical operations services and vendors.
- Experience with financial budgeting or reporting
- Strong collaboration and team-working, communication and organizational skills required
- Ability to take a leadership role and drive quality progress.
- Ability to interact with investigators, vendors, and individuals at all levels of the organization.

Success Factors

- Strong personal leadership skills to drive performance and support corporate objectives.
- 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.
- Creativity and resilience in problem solving.



- Relentless hands-on drive to implement and accomplish performance goals.
- Effective management of vendor partners to ensure project scope is achieved within defined budget.
- Ability to independently research, design, and implement platform technology solutions.

Compensation

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

The Acer Ethos

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.



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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.