Vice President, Clinical Development

Who We Are

This is an exciting opportunity to join Opus Genetics, a brand new, clinical-stage ophthalmic biopharmaceutical company dedicated to the development of gene therapies for rare inherited retinal diseases (IRDs). Our approach is based on validated science from pioneers in the ocular gene therapy space. Opus Genetics employs a unique, sustainable manufacturing approach and a commitment to leveraging our clinical network to reach patients and achieve optimal treatment outcomes.

The Role

The Vice President, Clinical Development will be the primary point person for medical oversight of clinical studies with responsibilities to include clinical trial design, feasibility assessment, protocol development, medical monitoring, review and interpretation of clinical trial data, drafting key clinical documents such as protocol, Clinical Study Report, briefing package, Investigational New Drug applications, Biologics Licensing Applications, etc. The VP will engage in shaping the company's global clinical development strategy to meet Opus goals. This role will be responsible for timely execution of deliverables in close collaboration with relevant internal and external partners.

The VP will partner with the cross-functional team to define and execute the clinical development project strategy, manage, and communicate program status for clinical development deliverables. Responsibilities include leading clinical development, building clinical program timelines and assuring key clinical development deliverables, and utilizing management tools for improving transparency and efficiency across the organization. This role involves close coordination with stakeholders within research and development (e.g., Regulatory Affairs, Medical Writing, Chemistry Manufacturing and Controls, Non-Clinical, Clinical Operations, Program Management) and outside of development (e.g., Finance, Legal).

The successful candidate is driven, curious, patient focused, collaborative, with a bold ambition to contribute to Opus' mission to enable normal lives for people living with inherited retinal diseases. Excellence in verbal and written communication, teamwork, and collaboration is a must.

Key Deliverables

The highly motivated, goal and results-oriented VP, Clinical Development will:

- Provide clinical scientific leadership for the clinical study team.
- Provide medical leadership for cross-functional workstreams including pharmacovigilance, biostatistics, clinical operations, regulatory affairs, etc.
- Provide medical safety oversight of CRO medical monitors.
- Collaborate with pharmacovigilance partners in the analysis of clinical trial safety data.
- Collaborate closely with partners in Clinical Operations, and be accountable for clinical trial conduct and timelines for associated key deliverables.
- Lead the design and writing of clinical protocols and associated clinical documents.
- Lead the writing of clinical and safety sections of key Program documents including Investigational New Drug submissions, Investigator Brochures, Clinical Study Reports, Development Safety Update Reports, Biologics License Applications, and other regulatory submissions and responses.
- Be responsible for the preparation, analysis, and presentation of safety data to internal and external safety monitoring boards.
- Assume primary responsibility for presentations related to clinical trial data and assist in the preparation of meeting abstracts, posters, and presentations related to clinical trial data.
- Contribute to the writing of manuscripts and publications.
- Adhere to ICH, Good Clinical Practice, and relevant regulatory guidelines.
- Provide medical leadership for internal audits and regulatory inspections.
- Assist in preparation of materials for Advisory Board meetings, investor meetings, Board of Director meetings, etc.
- Define and execute the global clinical development strategy for the growing Opus R&D pipeline, ensuring well-vetted clinical development strategies developed utilizing internal and external expertise.
- Represent Opus externally and build strong relationships with investigators, Key Opinion Leaders, regulators, and partners to promote Opus Genetics as the “IRD sponsor-of-choice.”
- Recruit, develop and lead Clinical Development talent, including ability and willingness to hold key team members accountable for progress with program goals; enable a team mindset for self-growth and the growth of other team members.

Skills and Expertise Required

- MD, DO, OD or non-US equivalent of MD degree.
- Completion of residency in Ophthalmology or equivalent is desirable with additional training in retina and/or inherited retinal degenerations highly desired
- 10+ years experience in early- to late-stage development in an academic or industry (CRO and/or Biotech) setting. Proven ability to:
    - Plan and conduct clinical trials

- Deliver high-quality results within established timelines
- Demonstrated track record in in working effectively in cross-functional teams and work streams (pharmacovigilance, biostatistics, clinical operations, and regulatory affairs).

- Attention to detail, internal drive to generate high-quality work, and sense of passion and urgency to achieve team and program goals.
- Excellent analytical, problem-solving and strategic planning skills.
- Integrated understanding of FDA, EMA, ICH, and GCP guidelines. Prior interactions with FDA and EMA regulatory agencies is desirable.
- Excellent interpersonal, oral, and written communication skills.
- Demonstrated leadership and ability to influence across all levels of a cross-functional team without direct managerial relationship.
- Demonstrated ability to perform at a strategic level as well as in a hands-on capacity.
- Ability to drive decision-making and ability to create a strong collaborative dynamic.
- Display poise and self-confidence to interact with partners, decision boards and conduct difficult conversations if needed.
- Experience in risk assessment, negotiating, and problem solving/mitigation.
- Ability to work in fast paced emerging gene therapy environment and exemplify Opus Genetics core values of Integrity, Honesty, Transparency, Teamwork, Learning, Urgency, and Diversity & Inclusion.