Senior Director, Clinical Development

About Us
Glympse Bio is pioneering the development of synthetic biomarkers – biochemical sensors developed using breakthroughs in science, engineering, medicine and artificial intelligence – that are engineered to be perfectly tunable to any disease and offer earlier measures of response to disease and treatment. Our synthetic biomarkers are administered to patients and tailor-made to query the activity of key biological targets such as proteases – a class of enzymes that drive critical disease pathways. We are building a novel biomarker technology platform from the ground up, laying the foundation for innovative diagnostics which combines nanotechnology with AI to improve the lives of potentially millions of patients worldwide.

We are a vibrant and dedicated team working at the forefront of scientific discovery and clinical development. We are agile, resilient, and creative problem solvers. We are committed to bringing the best products to patients and at Glympse you will have the opportunity to work alongside a high functioning, interdisciplinary and collaborative team to develop an entirely new diagnostic modality.

Position Summary
Reporting to the CMO, this organizational leader will lead the clinical development function in cross-functional project and program development for our leading indication, NASH, as well as other potential future disease indications. Significant experience on study concept and protocol design, regulatory filings, clinical publications and presentations is required. Demonstrated excellence in complex project management and effectively managing multiple clinical project deliverables and priorities through matrix management and leadership are essential for this independent, remote role.

Responsibilities

- Lead the development of protocols and amendments as well as development and management of timelines and resource planning, supporting large clinical programs.
- Independently author clinical/regulatory documents such as protocols and amendments, CSRs (all phases), and IBs according to regulatory requirements.
- Oversee contract medical writers on protocols and amendments to ensure the highest quality of medical writing.
- Participate in development/improvement of document standards, templates, and processes and other non-medical writing activities.
- Provide high level and complex scientific and clinical guidance to Clinical Trials Management, Biostats, Regulatory and CRO Project Management staff to meet project deliverables and timelines.
- Provide high level input to trial protocol design and clinical study reports as well as Health Authority inquiries.
- Provide ongoing clinical medical monitoring for clinical trials including but not limited to assessment of eligibility criteria, site management and QC.
- Adhere to regulatory requirements of study conduct and industry standards of Good Clinical Practice as well as Glympse SOPs.
- Manage the clinical research component in the preparation/review of regulatory documents, annual reports, safety reports, Investigator Brochures and development plans.
- Coordinate the collection and assimilation of ongoing data for internal analysis and review.

- Coordinate and manage the preparation and/or review of data listings, summary tables, study results and scientific presentations.
- Present scientific information at clinical study investigator meetings, internal, and external meetings.
- Leads cross-functional strategic initiatives.

Qualifications

- MD or PhD in relevant field and 5+ years of relevant experience in clinical research in drug development, pharma, biotech, or academic clinical trials
- Ability to work effectively in a multidisciplinary team to cultivate an inclusive environment of respectful, open, honest dialogue and to foster a robust sharing of ideas and creative problem solving
- Ability to think analytically and strategically to formulate, develop, and execute clinical plans
- Possess a well-developed sense of integrity, strong work ethic, scrupulous attention to detail, clear ability to establish and maintain timelines, and persistent commitment to ensuring a high level of quality
- Excellent scientific written and oral communication and interpersonal skills are required
- Must be capable of working with attention to detail in a time sensitive environment
- Strong familiarity with good clinical practices and International Conference on Harmonization Guidelines is required.
- Experienced with Microsoft Office (Excel, PowerPoint, etc.) as well as job related programs
- Ability to partner, influence and inspire others.
- Ability to travel domestically and internationally ***once COVID19 restrictions are lifted*** to company, scientific, regulatory, investigator, and other meetings (~10-20% travel expected).

Desired Skills:

- Familiarity with clinical hepatology, specifically NASH
- Direct experience in the strategic, and tactical implementation of drug development
- Experienced with engaging internal and external expert physicians, scientists, and other key stakeholders, including community and civil society leaders, in constructive scientific and clinical dialog around study design, study conduct, and interpretation of clinical results
- Successful leadership and management experience
- Experience in business development and assessment of opportunities

The Ideal Candidate:

- Brings courage, character, humility, and energy to work every day
- Is motivated to improve the lives of the people they serve
- Is excited about what might be possible, sees problems as challenges to be overcome, and is driven by curiosity and creativity
- Is optimistic and committed to Glympse's mission

EEO Disclosure:

We are an equal employment opportunity employer. All qualified applicants will receive consideration for employment without regard to age, color, creed, disability, gender identity, national origin, protected veteran status, race, religion, sex, sexual orientation, and any other status protected by applicable local, state, or federal law.