Medical Director, Clinical Development

Syros Pharmaceuticals is pioneering the understanding of the non-coding region of the genome to advance a new wave of medicines that control expression of disease-driving genes. Syros has built a proprietary platform to systematically and efficiently analyze this unexploited region of DNA in human disease tissue to identify and drug novel targets linked to genomically defined patient populations. Because gene expression is fundamental to the function of all cells, the Company's gene control platform has broad potential to achieve profound and durable benefit across a range of diseases. Syros is focused on cancer and immune-mediated diseases and is advancing a growing pipeline, including its lead drug candidates SY-1425, a selective RARα agonist for genomically defined subsets of patients identified by its platform, for a range of cancers including acute myeloid leukemia and myelodysplastic syndrome, and SY-1365, a selective CDK7 inhibitor for a range of blood cancers and solid tumors. Led by a team with deep experience in drug discovery, development and commercialization, Syros is located in Cambridge, Massachusetts.

The Medical Director, Clinical Development, reporting to the CMO, will be responsible for developing the clinical development strategy for projects within the Syros Gene Control Portfolio. Lead clinical projects are currently advancing in Oncology, while opportunities for additional programs in non-oncology therapeutic areas are also being pursued. In addition to strategic clinical leadership for one or more drugs in the Syros development portfolio and input for the various programs which include companion diagnostic initiatives, the individual will collaborate with the clinical sciences, translational medicine, biostatistics, clinical pharmacology, clinical operations, data management, safety, regulatory, discovery and commercial representatives of the project development team to develop innovative clinical trial protocols that will deliver the development strategy efficiently. The medical director will interpret clinical trial data, together with members of the study team, in the context of emerging external information regarding the relevant treatment and regulatory landscape, and provide clinical expertise to support the program(s) by interacting with external opinion leaders, research scientists and clinical investigators.

Principal Responsibilities

- Applies clinical research and medical knowledge to create clinical development strategies
- Reviews and interprets trial data (safety, efficacy, PK/PD, translation biomarker, HR-QOL) with the clinical scientist and other study team members and communicates results to internal and external stakeholders

- Provides medical oversight and clinical guidance to support development and review of clinical protocols, Investigator Brochures, Informed Consent Forms and Clinical Study Reports
- Provides clinical input for review of safety data, protocol deviations, clinical study reports, with responsibility for the content of various clinical components to support global regulatory submissions
- Provides clinical input to study teams on Case Report Form design, statistical analysis plans, monitoring guidelines, Data Review Plans, and Quality Management Plans as needed, and tracks the emerging efficacy and safety profile of the drug
- Works with Development Operations, Clinical Research Organizations and CRO Medical Monitors to identify and select clinical sites, investigators, patient populations, and the recruitment strategy to meet goals in a time- and cost-effective manner and to enable quality, compliance and patient safety at the trial, site and patient level
- Partners with Safety/PV to ensure effective and timely completion and documentation of SAE reports, ASEs, targeted medical events, and cumulative and aggregate safety reviews
- Provides medical monitor advice to address medical questions/problems which may arise (e.g. eligibility questions) to enable quality, compliance and patient safety and to assure integrity of trial data
- Reviews and addresses significant protocol deviations (PD), PD trends and Significant Quality Events
- Reviews Investigator Initiated Research and Compassionate/Extended Use proposals upon request based on subject matter expertise
- Serves as a subject matter expert of the principles of clinical development, including the medical disciplines of hematology, oncology, immunology, autoimmune disorders and various rare diseases
- Serves as line manager for one or more Clinical Scientists in the clinical development organization
- Fosters relationships with external experts, and remains current with the literature, and with the competitive scientific, clinical treatment and regulatory landscape
- Supports discovery preclinical science to assure appropriate clinical input guides pipeline advancement and translational strategies
- Supports clinical contributions to corporate objectives including various business development activities
- Supports scientific and clinical advisory board meetings, publications and communications strategies
- Contributes to process improvement initiatives as Syros matures into a clinical stage biotechnology company
- Fosters an environment that thrives on intellectual challenges and seeks opportunities to mentor others in the organization on clinical perspectives and opportunities for drug development

Qualifications

Required:

- MD with minimum of 5+ years of clinical development experience in the pharmaceutical industry
- Experience in clinical development of targeted therapies with biomarker patient selection strategies and clinical translational strategies
- Excellent written and oral communication skills
- Ability to relate well to colleagues and associates both inside and outside the company

Preferred:

- Prior Oncology/Hematology clinical development or equivalent experience
- Postgraduate training/certification/fellowship in medical oncology and/or hematology or relevant subspecialty of internal medicine
- Development experience in immunology, autoimmunity, rare diseases is also desirable
- Scientifically oriented clinical drug developer experienced in collaborating with basic scientists, supporting discovery research and development of translationally focused preclinical strategies
- Thorough understanding of local and international regulations applicable to clinical development
- Practical experience in clinical trial strategies, methods, and processes
- Track record of designing and interpreting development plans and clinical studies
- Experience with global regulatory submissions

Technical Competencies-Specific Skills:

- Ability to design, initiate, and conduct clinical studies
- Demonstrated technical, administrative, and project management capabilities
- Ability to review and understand the emerging safety and efficacy profile of the drug candidate
- Demonstrated understanding of the complexities and recent developments in the relevant therapeutic/technical area, and the ability to apply such knowledge to drug development
- Demonstrated ability to present clinical data, study plans and tactics clearly and accurately to internal and external stakeholders
- Experience supporting a primarily outsourced clinical development organization
- Flexibility to manage and contribute to multiple projects in a fast-paced research environment