The Senior Clinical Scientist – Hematology/Oncology reports through the Clinical Science function which provides scientific expertise necessary to design and deliver clinical studies and programs.

- Responsible for implementation, planning, and execution of assigned clinical trial activities. Serves as Clinical Trial Lead for one or more trials
- Successfully leads, plans, and executes trial level activities for multiple trials with minimal to moderate level of supervision
- Provides scientific and clinical leadership to team of supporting Clinical Scientists (matrix leadership)
- Co-Leads study team meetings in partnership with GDO protocol manager; and collaborate with cross functional study team members
- May support clinical development planning (collaboration with Clinical Development Lead/Clinical Trial Physician for provision and analysis of data to support future planning)
- Maintain a thorough understanding of assigned protocols and protocol requirements; educate supporting team members
- Plan and lead the implementation all study startup/conduct/close-out activities as applicable
- Evaluate innovative trial designs (collaboration with Medical Monitor/Clinical Development Lead)
- Protocol and ICF development process with minimal guidance; including writing, reviewing, adjudication/resolution of cross functional comments and ensuring high clinical quality (collaboration with Medical Writing)
- Site-facing activities such as training and serving as primary contact for clinical questions
- Activities related to data generation and validation, including CRF design, clinical data review/query resolution; ensure consistent, quality data review by supporting CS team
- Develop clinical narrative plan; review clinical narratives
- Provision of information required by Protocol Manager for development of trial budget, CRO scope of work, etc.
- Review development of site and CRA training materials and presentation at SIV and Investigator meetings and support on Study committee (e.g., DMC) activities
- Drafting/review and validation of clinical study reports (CSRs) and clinical portions of Regulatory Documents (e.g., IB, DSUR, regulatory responses)
- Collaborate and serve as primary liaison between external partners for scientific advice

Qualifications:

- Degree in Life Sciences (MD, PhD, Pharm D, MS, RN or other scientific field preferred)
- 5+ years of experience in clinical science, clinical research, or equivalent
- Proficient knowledge of GCP/ICH, drug development process, study design, statistics, clinical operations
- Proficient knowledge and skills to support program specific data review, trend identification, data interpretation
- Knowledge of the establishment and operation of data monitoring committees, dose review teams, and independent response adjudication committees
- Excellent verbal, written, communication and interpersonal skills
- Must be able to effectively communicate and collaborate across functions and job levels
- Ability to assimilate technical information quickly
- Strong sense of teamwork; ability to lead team activities
- Proficient in Medical Terminology and medical writing skills
- Proficient knowledge of the disease area(s), KOLs, indication(s), compound(s) under study
- Proficient critical thinking, problem solving, decision making skills
- Understanding of functional and cross-functional relationships
- Commitment to Quality
- Adaptable / Flexible - willing and able to adjust to multiple demands and shifting priorities as well as an ability to meet day-to-day challenges with confidence and professionalism
- Proficient planning/project management skills (ability to develop short to mid-range plans that are realistic and effective in meeting goals)
- Proficient in Microsoft Word, Excel, PowerPoint, Electronic Data Capture, J-Review or similar data reporting tools

Domestic and International travel may be required.