At Astellas, we believe that nurturing exceptional relationships with our employees delivers exceptional business results.

Everyone at Astellas has a responsibility for creating a brighter future for patients around the world. From the first moment, Astellas will inspire you to put this ethos into practice – with a positive, agile company culture and with well-defined ethical principles, values, and systems.

Everything we do is led by our company values of integrity, being patient centric, taking ownership, delivering results, and communicating openly. These values are essential to Astellas' relationship with its employees and now is an exciting time to join us as we continue to evolve as a cutting-edge, value driven life sciences innovator.

Position：Clinical Site Management Lead

Department：Clinical Operations

Line Manager：China SBOE and Site Monitoring Lead

Location：Beijing/ Shanghai

Purpose and Scope

- This position is accountable for the direct management of assigned monitoring/site management related clinical trial staff across all clinical trial types, which may include pre/post-POC interventional drug trials, Clinical Pharmacology normal healthy volunteer clinical trials, pre-approval access and post-marketing regulatory commitment trials (interventional and non-interventional).
- Accountable for the identification, onboarding, training and development of monitoring clinical trial talent to support the planning, initiation, execution and close-out of clinical trials with operational excellence. Individuals in this role will also provide leadership/mentorship, in a matrix setting, for activities that support clinical trial teams.

- This position is accountable to the Head, Early or Late Stage Site Monitoring & Management, and will provide input into departmental budget and resourcing strategies, including development and implementation of global processes and procedures, non-drug product initiatives, and coaching of monitoring staff during execution of development trials.
- This position provides functional leadership and management globally of < 12 direct reports

Responsibilities and Accountabilities

- Responsible for resource planning, recruitment, mentoring, development and retention of site monitoring & management staff
- Manages and allocates monitoring resources to trials and monitor performance on assigned trials for monitoring staff (up to 12 direct reports)
- Provides direction, leadership and learning opportunities to enhance individual development of direct reports in support of providing best-in-class site monitoring across the portfolio
- Provides oversight and guidance in completing monitoring and site management related activities according to agreed timelines and quality standards, including identifying areas for additional training and development
- Oversees adherence to timelines, standards, processes for work assigned to their staff
- Serves as a point of escalation for clinical monitoring/site management related topics or issues from their staff
- Oversees and provide guidance to Clinical Operations Leads and/or Clinical Trial Leads in regional Key Opinion Leader (KOL) interactions, communications; and submissions to Health Authorities within their region/country of responsibility, aligned to the overall asset strategy.
- Responsible for compliance of direct reports with training and identification and support for any training needs
- Facilitates and supports global trial monitoring operational standards and tools
- Anticipates, recognizes and facilitates problem solving to support site monitoring & management staff and rapidly addresses and mitigates potential performance issues
- Collaborates effectively with portfolio operations Leads, clinical operations leads, Center of Excellence and PECs leadership to ensure site monitoring & management staff are delivering as expected and to ensure common framework and standards across clinical programs and trials
- Ability to collaborate with peers in Clinical Operations across Early and Late-Stage Clinical Operations, cross-functionally and regionally, including relevant counterparts globally, to align on best practices for clinical monitoring staff

- Identifies, escalates, and facilitates process improvements relevant to clinical trial monitoring and site management
- Contributes to development and implementation of best in class monitoring/site management standards and processes
- Responsible for overseeing, developing and aligning resources to ensure effective monitoring of clinical trials and a robust talent pool

Required Qualifications

- BA/BS degree with at least 8 years of executing global drug development programs and trials
- Minimum of 4 years site monitoring and direct people management experience
- Demonstrated leadership skills and ability to effectively collaborate with colleagues in Clinical Operations and cross-functionally to deliver on portfolio deliverables and objectives
- Must have extensive expertise in risk based monitoring strategies and strong knowledge of ICH/ GCP guidelines and multinational clinical trial regulations
- Must have experience working across multiple phases of development and in multiple therapeutic areas
- Demonstrated ability to successfully identify and lead global process or system improvement initiatives
- Must have a strong knowledge of clinical development processes and conducting global clinical programs
- Must have proven leadership skills and effective written and verbal communication skills
- Fluent in English. Depending on hiring region, may also be required to be fluent in local language.
- Moderate (~30%) travel required