

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: Data Management Lead

Department: Data Management

Line Manager: Head, Data Management PF Area

Location: Beijing/ Shanghai

Purpose and Scope

The position acts as a data management lead and represents Quantitative Sciences and Evidence Generation (QSEG) as the data management (DM) key contact in clinical study team meetings and some extended team discussions. This role is responsible for study level data management activities within a drug development program. This includes all aspects of study level DM deliverables (data standards, eSource, Medical Coding, database build, external data, central monitoring, etc.), and overall management/oversight of all data management activities for assigned projects. The individual ensures that studies within the program are executed within the agreed timelines and according to the agreed global standards and processes. The

individual has full accountability for the DM deliverables across multiple studies and is responsible for all vendor oversight for any outsourced DM activities.

The position contributes expert level Data Management knowledge and consultation to the clinical program team, as well as to other stakeholders within Development. This role may act as a key contact and lead of DM process and technical/systems improvement initiatives. 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).

Responsibilities and Accountabilities

- Very strong subject matter expertise in the Data Management (DM) discipline. Can support multiple studies concurrently with little to no oversight by functional manager.
- Advocates the DM position on technical processes within study team meetings. Shares DM process knowledge with study team colleagues and cross functional peers.
- Oversees multiple DM vendors and provides training and subject matter expertise to lower-level DM peers.
- Leads by example by providing data management expertise and input into drug development programs.
- May act as a functional DM expert for a specific DM specialty area, such as data standards, Medical Coding, eSource, external data, data visualization and analytics, etc.
- Review Key Risk Indicators (KRIs) outputs in aggregate across sites, regions and countries. As needed, review study level operational and patient data to support the investigation and root cause analysis of observations.
- Support the team in assessment of centralized monitoring observations to identify potential issues and risks occurring during study conduct.
- Performs vendor oversight activities across multiple studies. Reviews and gives input in vendor oversight processes. Proactively shares and provides suggestions on how to improve vendor oversight. Uses metrics and key performance indicators (KPIs) to monitor vendor performance.
- Documents any process related deviations and communicates to functional manager. Triggers discussion or takes immediate action if there are concerns with respect to quality of DM

deliverables.

- Expert cross-functional understanding on the impact of data management processes to other stakeholders.
- Leads the data review meetings for all data sources with Medical, Clinical Operations, Biostatistics, and Programming to highlight and discuss deviations to the protocol and specific data values relevant for the analysis/determining subject populations.
- Strong understanding of regulatory requirements, such as GCP, and how they impact Data Management activities and outputs

Required Qualifications

- Bachelor's degree in biological science, health-related or computer science field (or equivalent experience).
- Typically 8+ years of relevant experience in pharmaceutical, clinical research, or health services industry, including at least 6 years as a Data Manager with progressive leadership responsibility.
- Demonstrated expertise in Data Management from program inception through regulatory submission (regulatory submissions experience preferred).
- Recognized leadership and subject matter expertise in Data Management related global process improvement initiatives.
- Extensive experience with external data management and digital health solutions (e.g., eSource, eCOA, eConsent), including edata processes, central monitoring tools, and risk-based quality management (RBQM) principles.
- Advanced understanding of clinical data standards (e.g., CDISC) and ability to apply standards across studies and programs.
- Strong computer skills including database management software, reporting tools, and medical coding systems.
- In-depth knowledge of different data sources in clinical trial settings and associated data quality considerations.
- Prior inspection and audit experience.
- Proven project management and organizational skills to prioritize and direct work for self and others to meet timelines.
- Ability to influence and guide study teams, driving decision making and issue resolution across functions and vendors.
- Demonstrated critical thinking and sound judgement in complex or ambiguous data management

scenarios.

- Demonstrated learning agility and ability to drive adoption of new technologies and capabilities for Data Management

Preferred Qualifications

- SCDM Certified Clinical Data Manager (CCDM) preferred.
- Experience with RAVE, eClinical Solutions illuminate and CluePoints is a plus.