

Title: Director, Data Management

Location: Beijing, China

MISSION

- To provide accurate, high quality databases fit for purpose for worldwide Development of clinical trials within agreed timelines, and compliant with guidelines and regulations.
- To implement new processes and state-of-the-art technologies in order to improve data management effectiveness and efficiency, process clinical trial data on time, and help get the drug faster on the market.

KEY TASKS & RESPONSIBILITIES

- Contribute to the definition of the departmental mission, objectives and performance tracking globally
- Ensure consistency and harmonization in work and deliverables across trials and sites
- Ensure compliance with quality standards, guidelines and procedures
- Perform line management for local managers in DM, including:

- à Define staff objectives and evaluate performance

- à Prepare staff development and training plan

- à Motivate and build team spirit

- à Distribute work assignments in compliance with the strategy

- à Administer contracts for temporary personnel

- à Determine resource allocation and hiring needs

- à Ensure adequate resource allocation and prioritization to meet project timelines

- à Work with other line manager and Trial Data Managers to ensure adequate resource allocation and prioritization to meet project timelines

Select, direct and supervise contract staff for performance of outsourced operational activities in agreement with the head of Global DM

- à Develop and maintain capabilities to meet resource needs and use in-house, in-sourced and out-house staff as appropriate

- à Oversee outsourcing, participate in Oversight Committees with CROs, if applicable

- à Participate in the elaboration of the departmental strategy

System maintenance or process improvements

- à Lead and contribute to the continuous improvement, re-engineering and implementation of processes, tools, technologies, conventions, standards, policies, Standard Operating Procedures (SOPs), Working Instructions (WIs) and User Manuals as needed
- à Identify, evaluate and contribute to new processes and technologies that align DM activities with the goals of Global Clinical Operations organization
- à Monitor and evaluate departmental performance metrics
- à Keep up to date with job related topics
- à Be up to date with SOPs, WIs, and user manuals and maintain training log

EDUCATION/LANGUAGES

- Degree in a scientific discipline or health related field (Master Degree, university) or equivalent
- Excellent knowledge of English

PROFESSIONAL SKILLS & EXPERIENCE

- Proven experience in clinical data management in the pharmaceutical/biotechnology industry, equivalent to 10 years.
- Management/Supervisory experience
- Successful completion of multiple trials from beginning to end providing a full scope of DM experience
- Familiarity, InForm with DM systems e.g. ClinTrial
- Basic knowledge of SQL is a plus
- Excellent understanding of the clinical development process in the pharmaceutical industry
- Excellent understanding of relevant regulatory guidelines (e.g. ICH, FDA, EMEA) and Good Clinical Practice
- Experience with international and global teams.