spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Clinical Information Manager

SPAULDING CLINICAL aims to be the clinical research organization by which all others are measured. Pioneering in our approach to redefining how the industry perceives and achieves success; passionate in our pursuit of ingenious solutions that mitigate risk; loving in our care for our volunteers, customers and employees; and heroic in our ambitions to ensure the health and safety of people around the globe - Spaulding Clinical is taking ***research beyond results*** to create a marketplace of safer drugs.

Original Date: 25 Sep 2012

Revision Date:

Job Summary:

The CIM (Clinical Information Manager) will provide specialized knowledge and detailed attention to lead and carry out data management and data review activities in support of one or more clinical research studies.

Essential Duties and Responsibilities:

- Work within clinical study teams as an extended team member to define project timelines in the execution of clinical data management operations.
- Collaborate with peers within and outside the organization to pro-actively manage information availability and integration.
- Conduct work activities in compliance with all relevant regulations, ICH, and CFR guidelines as well as all Spaulding policies and procedures.
- Use defined department metrics as a framework for timely and quality clinical information management deliverables.
- Responsible for the role which includes executing the design, documentation, testing, and implementation of information collection systems and processes in support of the clinical study teams.
- Conduct training of study site personnel in eCRF completion, and data clarification processes.
- Coordinate of information management review activities and ensuring completion of all activities leading to the Study Database Lock.
- Responsible for the role which includes the execution of the data review strategy for one or more studies as defined by the individual study Data Management Plan.
- Initiate and manages the data clarification process, coordinating with other stakeholders to ensure appropriate resolution to all data clarifications prior to database lock.
- Create the clinical information management study documentation (e.g. Data Management Plan, Edit Check Specifications, etc.), and manage the review in accordance with existing standards.

- Responsible for the representation of the clinical data “information” management & programming organization in one or more clinical studies.
- Responsible for the implementation of quality, efficient, and consistent approaches to carrying out clinical information management tasks.
- Delivers training to clinical information management and other departments, as necessary.
- Able to travel 10%
- Able to meet challenging milestones

The Statements made in the job description are intended to describe the general nature and level of work being performed by people assigned to this job. These statements are not intended to be an exhaustive list of all responsibilities, duties and skills required of people assigned to this job.

Skills/Qualifications

- Ability to read, write, and interpret the English language.
- Computer skills (word processing, spreadsheets, graphics, PowerPoint)
- Analytical and problem solving skills
- Ability to multi-task and prioritize
- Planning, organizational, and project management skills
- Document writing skills Attention to detail with high quality outputs
- Negotiation skills Conflict management skills
- Proactive and critical evaluation of varied and multiple aspects of trial implementation to ensure timely completion and with requisite quality.
- Knowledge and understanding of regulatory guidelines for the use of computer systems in clinical trials
- Knowledge and understanding of SDTM and other industry standard data specifications.
- Knowledge of Research & Development and an understanding of regulatory guidelines/requirements related to R & D (e.g., ICH, GCP, safety reporting)
- Working knowledge of global standards related to clinical study data management activities (CRF design, data standards, database design, coding and coding dictionaries, etc.)
- Experience with Alphadas clinical database a real plus

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of the job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

- Ability to sit, stand, walk, reach with hands and arms, and use hands along with fingers, to handle or feel.
- Ability to lift and/or move up to 25 pounds.
- Specific vision abilities required by this job include clarity of vision both near and far.
- Ability to identify and distinguish colors.

Hazards:

- Potential for exposure to toxic or caustic chemicals
- Potential for exposure to blood borne pathogens

Education and Experience:

- Degree or equivalent experience in Clinical Research, Computer Science, Project Management or related field: 8 years experience, BS/BA degree with 6 years experience, or MS degree with 4 years experience.
- Minimum 2 years experience in a project lead role within a clinical data management organization, preferably within medium-large pharma or CRO.

Spaulding Clinical Research management has the discretion to hire personnel with a combination of experience and education which may vary from the above listed skills and qualifications.