spaulding clinical
RESEARCH BEYOND RESULTS

Job Description

Clinical Study Designer

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: 01Jul2015

Revision Date: 20 Mar 2019

Job Summary:

The Clinical Study Designer will provide specialized knowledge and detailed attention to lead and carry out clinical systems set up and E-source study activities in support of one or more clinical research studies.

Essential Duties and Responsibilities:

- Working within clinical study teams as an extended team member to assist in the execution of clinical data management operations.
- Collaborates with peers within the organization to pro-actively manage data capture and integration for data specified in study protocol.
- Conducts work activities in compliance with all relevant regulations as well as all Spaulding Clinical policies and procedures.
- Accountable for creation of clinical form content, which involves close communication with Clinical Research Coordinators (CRC's) and Project Data managers (PDM's), referencing the completed Data Collection Module (DCM), and standardization/refinement of forms and DCM, as needed.
- References approved Event Schedule from the CRC to assemble a complete and accurate Activity Plan for study use.
- Responsible for accurate subject slotting, based on the Check-In and Enrollment Lists supplied by the PI and Subject Selection (may be delegated to other trained clinical staff).
- Coordination of Clinical Systems setup and Review activities to ensure completion of all activities leading to the Study Completion.
    - Ensure that full study builds are completed.

  - Ensure that key department reviews are completed.
- Assist with clinical data management study documentation (e.g. Data Management Plan, Edit Check Specifications), and supporting the review in accordance with existing standards.
- Responsible for the implementation of quality, efficient, and consistent approaches to carrying out clinical systems tasks.
- Delivers training to clinical staff, other departments and outside agency groups, as necessary.
- Ability to meet challenging milestones.
- Provides a bridge between Clinical Staff and Data Management, which may involve facilitating meetings or trainings with apparat team members.
- Responsible for sample label association for clinical labs, PK/PD/PG samples, dosing labels, etc.
- Responsible for trouble-shooting Forms and Activity Plans as needed.
- Responsible for reviewing and improving Clinical System standards.

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:

- Computer skills (word processing, spreadsheets)
- Preferred programing experience (C#, Java, JavaScript)
- Preferred knowledge of Clinical Systems (ClinSpark) or another eDC
- Analytical and problem-solving skills
- Ability to multi-task and prioritize
- Planning, organizational, time management, and project management skills
- Document writing skills
- Attention to detail with high quality outputs
- Conflict management skills
- Proactive and critical evaluation of varied and multiple aspects of trial implementation to ensure timely completion and with requisite quality.
  Ability to adjust to protocol changes and ensure up-to-date DCM.

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:

- One (1) year of Data Management experience preferred, but not required
- Degree in Information Management, Computer Science, Mathematics, Statistics, or related discipline preferred, but not required.
- High School diploma

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.

This is to acknowledge that I have read and understand the above job description. This copy supersedes any others previously distributed. I further understand that Spaulding Clinical may change, add or delete any essential duties and responsibilities described at its discretion with or without prior notice.

_____ _____

Employee Name (Printed) Date

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Employee Signature