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ROBERT SMITH

Sr. Clinical Research Associate

info@paulresume.com | LinkedIn Profile | Quid resume.com

Experienced multi-faceted Project Manager Associate Director professional with diverse background in pharmaceutical and medical device industries, leading multiple operational areas. Responsible for leading multiple operational areas of Clinical Trials to meet regulatory approvals.

EXPERIENCE

Sr. Clinical Research Associate

ABC Corporation - 2006 - 2008

- Managed startup and completion of activities associated with clinical research studies per FDA and ICH regulations and GCP requirements.
- Responsible for preparation of final study reports, statistical analysis plans, data management plans, and other required outputs leading to FDA approval and site initiation.
- Created, maintained and managed Trial Master Files for compliance. Managed clinical project functions through meeting, report, team meetings, study performance metrics or status, review and management.
- Responsible for managing financial aspects of the project including CRF, vendor and site payments, tracking and processing of payments.
- Reviewed and managed study sites ensuring site compliance of regulatory activities and integrity of clinical data in adherence to applicable regulatory guidelines and Standard Operating Procedures (SOPs).
- Enforced and ensured adherence to SOPs of all clinical sites.
- Participated in design and coordination of pre-clinical development projects, leading to future clinical trials and subsequent approval of new products.

Clinical Research Associate

ABC Corporation - 2005 - 2006

- Implemented and monitored clinical trials to ensure sponsor and investigator obligations were met and consistent with applicable local regulatory requirements and ICH guidelines.
- Visited sites to assess qualifications of potential investigators, initiate studies, onboard site personnel, review case report forms and ensure accuracy of data, and coordinate queries.
- Performed source document verification, reviewed case report forms, performed query resolution in a timely manner, and verified drug availability and quality at investigative sites.
- Performed investigator site file reconciliation, responding new and updated interrelated documents and releasing them for content.

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CLINICAL TRIAL MANAGER JOB DESCRIPTION

Job Description

Clinical Trial Manager is responsible for planning and executing clinical trials at medical institutions. The Clinical Trial Manager oversees clinical research operations and ensures that the trial is conducted in the most efficient manner. The Clinical Trial Manager is responsible for ensuring the trial is conducted in the most efficient manner and for ensuring that the trial is conducted in the most efficient manner.

Key Responsibilities

- Work with the project manager to establish budgets for training and other costs associated with the trial.
- Initiate and coordinate activities such as site selection, site initiation, and site monitoring.
- Coordinate and manage the trial budget and other resources.
- Ensure compliance with regulatory requirements and ICH guidelines.
- Monitor and report on trial progress and other key metrics.
- Manage the trial data and ensure data integrity.
- Coordinate with the sponsor and other stakeholders.
- Ensure compliance with regulatory requirements and ICH guidelines.
- Monitor and report on trial progress and other key metrics.
- Manage the trial data and ensure data integrity.
- Coordinate with the sponsor and other stakeholders.

Skills

- Strong understanding of clinical trial operations and ICH guidelines.

SAMPLE CRA CURRICULUM VITAE

John Smith, BA
 900 ABC Drive
 Alameda, CA 94501
 949-555-1212

Education

University of ABC
 Bachelor of Arts - Biology
 August 2000

Professional Experience

Clinical Research Associate
 ABC Corporation

11/2005 to present

Job Duties

- Monitor the conduct of clinical trials, especially enrollment and quality of data.
- Verify subject safety and site adherence to FDA Regulations and ICH GCP Guidelines.
- Ensure Adverse Events are reported appropriately, accurately and in a timely manner and that follow-up activities are conducted as necessary.
- Review CRF, informed consent documents, and query logs/parameters.
- Acquire specific clinical and therapeutic knowledge related to studies monitored.
- Conduct Qualification, Initiation, Interim and Closure monitoring visits.
- Ensure complete and thorough study drug reconciliation.
- Manage trip reports, letters, query resolutions and expenses.
- Manage site master file content and work with sites to ensure communication requirements between site and PIS are adhered to.
- Provide support and timely follow-up for all audit and quality assurance activities.

Clinical Research Associate II
 ABC Corporation

01/2004-11/2005

Job Duties

- Monitor Phase II trials.
- Verify subject safety and site adherence to FDA and ICH regulatory guidelines.
- Conduct the study initiation, interim and closure visits.
- Manage trip reports, letters, queries and expenses.
- Ensure complete and thorough study drug reconciliation.
- Initiated sites in the use and maintenance of an MRI and a CLA visit device.

Job Title: Medical Laboratory Assistant (MLA)
Location: TOL Pathology, Kuala Lumpur (KL) Head
Reporting: QA Supervisor
Accountable to: Pathology Manager

Overall Job Purpose: To assist in the daily running of the laboratory section in which you have been assigned under appropriate technical supervision. To maintain the highest professional and technical standards in the department.

Main Duties

To include, but not be restricted to, the following:

To become familiar with the day to day methods in use in the laboratory in which you are assigned. To put these methods into practice. To refer to your supervisor any problem which arises during the discharge of your primary duties outlined below.

- To carry out a range of routine technical and clerical duties within sample Reception.
- To carry out a range of other support duties for the laboratory.
- To receive, identify and prepare for analysis all incoming samples / request forms ensuring the data accuracy on the laboratory IT system.
- Answering telephone.
- Generating and printing of request forms.
- To maintain your own knowledge and skills to perform the job as detailed within this job description.
- Any other duties assign by the laboratory manager.

ROBERT SMITH

Clinical Research Associate/Assistant

Phone: 0123-456 789 | Email: info@doctors.com | Website: Doctors.com

SUMMARY

A dedicated and goal oriented clinical research associate, capable of using problem solving, creative ability, providing solid academic background and cross functional experience in clinical project management, product knowledge, time management, organizational and process improvement.

CORE COMPETENCIES

Microsoft Office

PROFESSIONAL EXPERIENCE

Clinical Research Associate/Assistant

ABC Corporation - August 2009 - October 2010

Key Deliverables:

- Assisted the data management groups and the project team in the processing of all clinical data by ensuring the timely collection of other aspects of job-related responsibilities data integrity resolution.
- Conducted site management activities, including but not limited to site activation visits, site activation visits, site training, site routine monitoring visits, and site close out visits.
- Collaborated with investigator and site staff to ensure that the protocol is being followed to ensure compliance for protocol deviations throughout the course of the study.
- Developed recruitment strategies and an enrollment plan with the investigator and site staff to meet recruitment goals in conjunction with the SOP and GCP guidelines.
- Ensured proper storage, disposition, and accountability of all investigational products and related reports.
- Ensure that reports are written and submitted via CTMS within 4 working days of visit.
- Participate in various sponsor or project team conferences and training sessions. Prepare for and attend Investigator Meetings. Responsible for the resolution of clinical data to ensure investigator and site compliance with the study (regulatory, local ethical standards, FDA regulations, CDISCOP Guidelines).

Clinical Research Associate

ABC Corporation - 2008 - 2009

Key Deliverables:

- Recruited and recruited potential investigators.
- Assisted investigator meetings.
- Performed site visits - site management, site activation, site testing and close out visits.
- Received informed consent for appropriate elements.
- Generated and updated data queries.
- Performed clinical and budget negotiations.
- January 2008.

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By Harlow Keith Updated December 1, 2021 Clinical Data Entry Associates are responsible for collecting information on patient medical records and clinical trials. Speed, accuracy, and attention to detail are the requirements that are listed in an associated data entry job description. If you are considering working as a clinical data entry associate, you have several options to address this career. Some employers even allow their employees to work from home, making this an attractive job opportunity for parents staying at home. Clinical Data Entry Associates work with computerized patient records and clinical trial data to ensure that it is accurately sorted and recorded. In addition to entering data, associates can also transcribe and send information according to the employer's specifications. If a record requires further research, the Associate will retrieve the information for the research team to evaluate complete, accuracy, and errors. Associates can also have access to sensitive patient information, so maintaining the integrity of records is also a very important responsibility. In the event of malfunctioning of the system, partners may be involved in troubleshooting actions. Most clinical data entry partners have a high school diploma or equivalent. While a university education is not necessary, some employers prefer job applicants with handwriting certifications or computer systems training. Employers are also looking for candidates who have had prior experience working with spreadsheet software and SPSS that analyze statistics, or for candidates who are simply very smart. Job applicants must be and independent with the ability to learn quickly and organize the information according to the client's specifications. Better-than-average typing speed with few errors is one of the most important skills that are listed in a description of associated data entry jobs. Many employers will ask their applicants to take a writing test before hiring. Entry of clinical clinical data They work on a variety of different office environments, but as more and more employers look for outsourcing to save costs, many jobs are held from home. The work can be performed by project or ongoing, according to the type of clinical data. Independent websites such as UPWORK.com or advertise work opportunities for teleworking workers who specialize in data entry. Research companies also employ data entry contractors for clinical trial work. As the patients' records and clinical data have been transferred to an electronic platform, the need for associates for the income of data in fact, the occupational information network, or ONET, is informed that jobs will decrease 1% on average each year up to 2030 according to the salary data compiled by the Office of Labor Statistics. The average salary for data entry by 2020 was a € 34,440A »per year, or« 16.56A »per hour. However, the skills of a trained data entry associate can be applied to other industries that are currently experiencing employment growth much better than average, such as clinical data managers. ONET indicates that jobs for these data professionals will grow a rhythm of 15% between 2020 and 2030. Clinical data managers earn an average annual salary of «98,230A» or Å «47,23» hour. The associates of data entry that are interested in moving forward in their careers to become data managers should consider obtaining a graduate title. Combined with the experience of data entry, having a university title opens the door to more employment opportunities, not only in the clinical and medical fields, but also in market research and insurance analyzes. picjumbo.com/pexels Work at a distance has gained strength in the United States during the years. In fact, between 2005 and 2017, the number of teleworkers increased by 159%, according to a study by FlexJobs. This trend has continued in recent years, as a growing number of workers seek the flexibility needed to be able to choose their working environment" and a growing number of workers are seeking the flexibility they need to choose their working environment, companies see the cost-saving potential of having at least part of their workforce operating off-site. As COVID-19 spread around the world in 2020, many employees with appropriate functions had the option to continue working remotely. However, other workers out there may be looking for new jobs or may be interested in switching to virtual jobs altogether. Finding out which ones are authentic can be difficult, but these virtual roles are in great demand "and are legitimate". There is a great demand for developers across the market, with many companies offering remote work opportunities. In fact, it points out that many developer jobs are also the hardest to fill, with front-end, full stack and mobile developer jobs doing the first six roles on demand. Danial RiCaRoS/Unsplash Every business has its own list of things it looks for in developers. Experience working with programming languages like Python and Java is almost always a necessity. But there are several different directions to take a career as a developer. For example, mobile developers create apps used on mobile devices. Front-end developers build websites by taking data and turning it into the site interfaces with which users interact. Back-end developers create the interactive elements of a website, including login options, such as images and creating accounts. Finally, full-stack developers work as front-end and back-end developers with extensive knowledge of software development, user experience, quality assurance and security.Virtual AssistantVirtual assistant jobs vary widely in their tasks and responsibilities. As a minimum, virtual assistants need a computer and an Internet connection, you will have to be a self-start with excellent organizing skills. After all, whoever hires you is looking for someone who can remove some of their stress. KOBU Agency/Unsplash The nature of the job depends on who you work for. Many virtual assistants are responsible for organising documents and Maintaining social media channels and managing billing and accounting issues Other common tasks include answering and directing phone calls, keeping up with email communications, managing calendars or schedules, and researching potential projects and clients.Medical TranscriberAs a medical transcriber, you take voice recordings made by health care professionals and convert them into written reports. Some people work in offices and hospitals, but many medical transcribers can work from home. In most cases, you need to have a good foundation in medical terminology and grammar. Most employers require candidates to have completed a post-secondary education course.Online marketing CoWomen/UnsplashDigital marketers are in demand. There has been a skill gap in the market for years, according to the Digital Marketing Institute. Some of the most sought-after skills include search engine optimization strategy, website development, brand marketing, content strategy, digital project management, and data analytics. Basically, it will be tasked to help businesses address, interact and attract consumers through the use of various online strategies. Campaign Creators/Unsplash For those with the skills needed to do these jobs well and the desire to potentially create a remote business, online marketing is a solid option. Some online marketers work as consultants who analyze a business's current online marketing plans to see where the company can improve. Others are hired to create and implement long-term online marketing strategies.DesignersGraphic design, web design, user experience and user interface tend to fall under the umbrella of design. It's not impossible to break into this remote Working with a minimum experience, but the most lucrative and stable designer works are often granted to candidates with the experience and knowledge necessary to carry out the work. Experts suggest choosing the type of design that you want to be and the that best suits your skills. Then, talk to other designers, take a class and practice your art. If you don't have a portfolio, start taking projects to create one.The Creative Exchange/Unsplash MORE ASKMONEY.COM ASKMONEY.COM

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