Clinical Research Associate II

Hiring organization
Precision for Medicine

Job Location
Remote, Oregon, United States

Base Salary
$ 95000 - $ 137500

Date posted
May 31, 2024

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Description

Position Summary:The CRA II is a seasoned, experienced professional in monitoring and site management. Responsibilities will be dependent upon the type and timing of the program to which the CRA II is assigned and typically include activities involving start-up and study implementation, on-site monitoring of clinical research studies as well as on-going site management. Incumbents work independently as a study team member. Essential functions of the job include but are not limited to: Oversees all aspects of study site management to ensure patient safety is protected, quality of data generated by managed sites resulting in consistently low query levels and in acceptable Quality Assurance reports. Provides guidance at the site and project level towards audit readiness standards and supports preparation for audit and required follow-up actions. Updates, tracks and maintains study specific trial management tools/systems, and status reports. If required, manages site start up procedures including the feasibility and recruitment of potential investigators, preparation of EC/IRB submissions, collection and review of regulatory documents, review and adaptation in Patient Informed Consents, notifications to IRB, EC and regulatory authorities, as appropriate, translation of study related documentation, organization of meetings and other tasks as instructed by the Clinical Trial Manager/Project Manager. If required, assists the negotiation of study budgets and the execution of investigator contracts under directions of Site Contract Management department/designee. Verifies the process of obtaining informed consent has been adequately performed and documented for each subject/patient, as required/appropriate. Assesses factors that might affect subject/patientâ??s safety and clinical data integrity at an investigator/physician site such as protocol deviation/violations and pharmacovigilance issues. Independently conducts all forms of site visits, including pre-study/ qualification, initiation, routine monitoring, and close-out visits, in accordance with the protocol, local laws, ICH-GCP and Precision SOPs. Prepares and submits for review, accurate and timely monitoring reports from all site visits (on-site and remote). Documents activities via confirmation letters, follow-up letters, trip reports, communication logs, and other required project documents as per SOPs, Clinical Monitoring Plan/Site Management Plan and client requirements. Supports subject/patient recruitment, retention and awareness strategies. Enters data into tracking systems as required to track all observations, ongoing status and assigned action items to resolution. Routinely reviews the Investigator Site File (ISF) for accuracy, timeliness and completeness. Reconciles contents of the ISF with the Trial Master File (TMF). Ensures the investigator/physician site is aware of the requirement of archiving essential documents in accordance with local guidelines and regulations. Communicates effectively and proactively with both site personnel and Precision Project and Clinical Trial Management to relay protocol/study issues including any deviations and implements necessary actions in response to those issues. Develops and maintains good working relationship with investigators and study staff, serving as an ambassador to promote Precision high quality and professional image. Performs investigational product (IP) inventory, reconciliation and reviews storage and security. Verifies the IP has been dispensed and administered to subjects/patients according to the protocol. Verifies issues or risks associated with blinded or randomized information related to IP. Applies knowledge of GCP/local regulations and organizational procedures to ensure IP is appropriately (re)labelled, imported and released/returned. Performs data review activities, including remote EDC CRF and patient profiles review, query resolution, and assists data management and clinical data quality personnel to resolve data discrepancies. Identifies and processes Serious Adverse Events according to the procedures defined by the study team. Also demonstrates a full understanding of

the SAE reporting process. Identifies site risks and escalates those to Clinical Trial Manager/Project Manager with suggested contingencies. Owns the timely and appropriate resolution of the risk with minimal support from project team. Prepares for and attends Investigator Meetings and/or sponsor face-to-face meetings. Participates in global clinical monitoring/project staff meetings (inclusive of Sponsor representation, as applicable) and attends clinical training sessions according to the project specific requirements. Travels as necessary according to project needs. Performs other duties as assigned by management. Qualifications:Minimum Required: Europe: University degree life science/pharmacy/other health related discipline or equivalent experience in a scientific or healthcare discipline or be a licensed health care professional. N. America: 4-year college degree or equivalent experience in a scientific or healthcare discipline. Two (2) years or more as a CRA in either a CRO or pharmaceutical/ biotech industry or equivalent, relevant experience and/or demonstrated competencies. Site management or equivalent experience in clinical research One year of oncology monitoring experience Other Required: Excellent communication and organizational skills are essential. A team player. Evidence of a client focused approach Experience using computerized information systems, electronic spreadsheets, word processing and electronic mail. Ability to travel overnight. Up to 60% travel on average, based on regional requirements. International travel as needed. Fluency in English and for non-English speaking countries the local language of country where position based Preferred: Graduate or postgraduate degree Oncology phases preferably in early phases Experience monitoring in rare and complex therapeutic areas Experience monitoring EDC trials and EHR records Experience in biopharma or relevant therapeutic area Relevant site start-up (feasibility, contract negotiations, submissions) experience for the particular country Ability to monitor study sites, with supervision, according to protocol monitoring guidelines, SOPs, GCP and ICH guidelines. Ability to resolve project related problems and prioritizes workload to meet deadlines with minimal support from management. Competencies: Exhibits self-motivation and is able to work and plan independently as well as in a team environment Understands clinical trials methodology, including a working knowledge of protocols and indications being studied Demonstrates professionalism as evidenced by punctuality, ability to deliver on commitments, an understanding of the service culture and positive interactions with customers and teammates, including good interpersonal skills Collects data of consistently high standard Demonstrated ability to conduct formal presentations to a wide variety of audiences including colleagues, investigative staff, and clients with a high level of proficiency Fluency in English and for non-English speaking countries the local language of country where position based Please mention the word **INTUITIVE** and tag RMTUxLjgwLjE0My4yMDY= when applying to show you read the job post completely (#RMTUxLjgwLjE0My4yMDY=). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they’re human.

Contacts

Job listing via RemoteOK.com