careerone

Sr CRA II with Lead responsibility - General Medicine

Syneos Health Australia • Home Hill QLD 4806

Base pay	Work type	Contract type
$0 - $0	Full Time	Permanent

Perks

TRAINING

Skills

PROJECT MANAGEMENT
ARCHIVING
BIOPHARMACEUTICAL
CLINICAL MONITORING
CLINICAL RESEARCH
CRA
DATA COLLECTION
GCP
ICH
ICH/GCP
PHARMACOVIGILANCE
CRA II

Full job description

Senior Clinical Research Associate II

Come discover what our 25,000 employees already know: work here matters everywhere. We're a growing and evolving biopharmaceutical industry leader, which means you'll have endless opportunities to work with experts around the world and build the career you've dreamed of.

Job details

Date posted
17 Jun 2021

Expired On
19 Jun 2021

Category
Science, Technology & Environment

Occupation
Clinical Research

Base pay
$0 - $0

Contract type
Permanent

Work type
Full Time

Job mode
Standard/Business hours

Desired education level
BACHELOR'S DEGREE

Work Authorisation
AUSTRALIAN CITIZEN / PERMANENT RESIDENT

As a part of the Syneos Health team, you'll help us deliver results for a rewarding reason - we improve patients' lives around the world. Because to us, a patient isn't just a number, they're our family, friends, and neighbors.

Why Syneos Health

• #SyneosHealthLife means we're committed to our Total Self culture - where everyone can authentically be themselves. Our Total Self culture is what unites us globally, and we know every person's unique contributions make a difference.

• We believe our success is a direct result of the people who are driving it - you! We value your dedication to care for our customers and patients, so we want to focus on taking care of you. That's why we offer a comprehensive benefits program encompassing your total health - physical, mental and financial.

• We are continuously building the company we all want to work for and our customers want to work with. Why? Because when we bring together diversity of thoughts, backgrounds, cultures, and perspectives - we're able to create a place where everyone feels like they belong.

Job responsibilities

• Performs site qualification, site initiation, interim monitoring, site management and close-out visits (performed on-site or remotely) ensuring regulatory, ICH-GCP and/or Good Pharmacoepidemiology Practices (GPP) and protocol compliance. Uses judgment and experience to evaluate overall performance of site and site staff and to provide recommendations regarding site-specific actions; immediately communicates/escalates serious issues to the project team and develops action plans. Maintains a working knowledge of ICH/GCP Guidelines or other applicable guidance, relevant regulations, and company SOPs/processes.

• Verifies the process of obtaining informed consent has been adequately performed and documented for each subject/patient as required/appropriate. Demonstrates diligence in protecting the confidentiality of each subject/patient. Assesses factors that might affect subject/patient's safety and clinical data integrity at an investigator/physician site such as protocol deviation/violations and pharmacovigilance issues.

• Per the Clinical Monitoring/Site Management Plan (CMP/SMP):

o Assesses site processes

o Conducts Source Document Review of appropriate site source documents and medical records

o Verifies required clinical data entered in the case report form (CRF) is accurate and complete via review of site source documents and medical records

o Applies query resolution techniques remotely and on site, and provides guidance to site staff as necessary, driving query resolution to closure within agreed timelines

o Utilizes available hardware and software to support the effective conduct of the clinical study data review and capture

o Verifies site compliance with electronic data capture requirements.

• May perform 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.
• 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.
• Documents activities via confirmation letters, follow-up letters, trip reports, communication logs, and other required project documents as per SOPs and Clinical Monitoring Plan/Site Management Plan. Supports subject/patient recruitment, retention and awareness strategies. Enters data into tracking systems as required to track all observations, ongoing status and action items to resolution.
• Understands project scope, budgets, and timelines for own and others' activities in the clinical team; manages site-level activities / communication to ensure project objectives, deliverables and timelines are met. Must be able to quickly adapt to changing priorities to achieve goals / targets.
• May act as primary liaison with study site personnel, or in collaboration with Central Monitoring Associate. Ensures all assigned sites and project-specific site team members are trained and compliant with applicable requirements.
• Prepares for and attends Investigator Meetings and/or sponsor face to face meetings. Participates in and may lead global clinical monitoring/project staff meetings (inclusive of Sponsor representation, as applicable) and attends clinical training sessions according to the project specific requirements.
• Provides guidance at the site and project level towards audit readiness standards and supports preparation for audit and required follow-up actions.
• May provide direct supervision, training and/or mentorship to more junior level CRAs. Performs training and sign off visits for junior CRA staff, as assigned.
• May be mentored and assigned lead tasks under supervision of an experienced Clinical Operations Lead (COL) or operational line manager. This could include participation in business development proposals and/or defense meetings.

• For Real World Late Phase (RWLP), the Sr. CRA II will use the business card title of Sr.Site Management Associate II. Additional responsibilities include:
o Site support throughout the study lifecycle from site identification through close-out
o Knowledge of local requirements for real world late phase study designs
o Chart abstraction activities and data collection
o As required, collaborate and build relationship with Sponsor and other affiliates, medical science liaisons and local country staff
o The SMA II may be requested to train junior staff
o Identify and communicate out of scope activities to Lead CRA/Project Manager

o Proactively suggest potential sites based on local knowledge of treatment patterns, patient advocacy and Health Care Provider (HCP) associations.
o Identify operational efficiencies and process improvements
o Develop study and country level informed consent forms
o Collaborate with RWLP Regulatory team to ensure updated regulatory information is applied and shared
o Participate in bid defense meetings
o Provide input into Requests for Proposals (RFPs), scope and budgeting. Develop site management strategy.
o Participate in Case Report Form design and edit check development.

What we're looking for
• Bachelor's degree or RN in a related field or equivalent combination of education, training and experience
• Knowledge of Good Clinical Practice/ICH Guidelines and other applicable regulatory requirements
• Must demonstrate good computer skills and be able to embrace new technologies
• Excellent communication, presentation and interpersonal skills. Moderate level of critical thinking skills expected
• Ability to manage required travel of up to 75% on a regular basis

Get to know Syneos Health
We are the only full-service biopharmaceutical solutions company in the world. That means we bring together the best clinical and commercial minds to create a better, smarter, faster way to get medicines into the hands of patients who need it most. Learn more about Syneos Health.

Additional Information:
Tasks, duties, and responsibilities as listed in this job description are not exhaustive. The Company, at its sole discretion and with no prior notice, may assign other tasks, duties, and job responsibilities. Equivalent experience, skills, and/or education will also be considered so qualifications of incumbents may differ from those listed in the Job Description. The Company, at its sole discretion, will determine what constitutes as equivalent to the qualifications described above. Further, nothing contained herein should be construed to create an employment contract. Occasionally, required skills/experiences for jobs are expressed in brief terms. Any language contained herein is intended to fully comply with all obligations imposed by the legislation of each country in which it operates, including the implementation of the EU Equality Directive, in relation to the recruitment and employment of its employees. The Company is committed to compliance with the Americans with Disabilities Act, including the provision of reasonable accommodations, when appropriate, to assist employees or applicants to perform the essential functions of the job.