Israel Jobs Expertini®

Experienced Clinical Research Associate (CRA)

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Company: Thermo Fisher Scientific

Location: Israel

Category: other-general

Monitors investigator sites with a risk-based monitoring approach: applies root cause analysis (RCA), critical thinking and problem-solving skills to identify site processes failure and corrective/preventive actions to bring the site into compliance and decrease risks. Ensures data accuracy through SDR, SDV and CRF review as applicable through on-site and remote monitoring activities. Assess investigational product through physical inventory and records review. Documents observations in reports and letters using approved business writing standards. Raises observed deficiencies and issues to clinical management expeditiously and follow all issues through to resolution. May need to maintain regular contact between monitoring visits with investigative sites to confirm that the protocol is being followed, that previously identified issues are being resolved and that the data is being recorded in a timely manner. Conducts monitoring tasks in accordance with the approved monitoring plan.

Participates in the investigator payment process. Ensures a shared responsibility with other project team members on issues/findings resolution. Investigates and follow-up on findings as applicable. Participates in investigator meetings as vital. May help to identify potential investigators in collaboration with the client company to ensure the acceptability of qualified investigative sites. Initiates clinical trial sites according to relevant procedures to ensure compliance with the protocol and regulatory and ICH GCP obligations, making recommendations where warranted. Performs trial close out and retrieval of trial materials.

Ensures that required essential documents are complete and in place, according to ICH-GCP and applicable regulations. Conducts on-site file reviews as per project specifications.

Provides trial status tracking and progress update reports to the team as required. Ensures study systems are complete, accurate and updated per agreed study conventions (Clinical Trial Management System).

Facilitates effective communication between investigative sites, client company and internal project teams through written, oral and/or electronic contacts. Responds to company, client and applicable regulatory requirements/audits/inspections.

Maintains and completes administrative tasks such as expense reports and timesheets in an accurate and timely manner.

Contributes to the project team by assisting in preparation of project publications/tools and sharing ideas/suggestions with team members.

Contributes to other project work and initiatives for process improvement, as required.

Education:
Bachelor's degree in a life sciences field.

Clinical monitoring experience that provides the knowledge, skills, and abilities to perform the job (comparable to 1-2 years) in a clinical environment where experience is gained in clinical trials, medical terminology, medical research, clinical research or health care or experience in a health sciences field with formal training in medical terminology and anatomy may be considered.

Valid driver's license where applicable.

In some cases an equivalency, consisting of a combination of appropriate education, training and/or directly related experience, will be considered sufficient for an individual to meet the requirements of the role.

Knowledge, Skills & Abilities:
Basic medical/therapeutic area knowledge and understanding of medical terminology.

Ability to attain and maintain a proven understanding of ICH GCPs and industry regulations

and procedural documents.

Good oral and written communication skills, with ability to communicate effectively with medical personnel.

Good interpersonal skills.

Ability to maintain customer focus through the utilization of good listening skills, attention to detail and the ability to perceive customers' underlying issues.

Good organizational and time management skills.

Ability to remain flexible and adaptable in a wide range of scenarios.

Well-developed critical thinking skills, including but not limited to: critical mindset, in-depth investigation for appropriate root cause analysis and problem solving.

Ability to manage Risk Based Monitoring concepts and processes.

Ability to work in a team or independently as required.

Good digital literacy: proven knowledge of Microsoft Office and ability to learn appropriate software.

Good English language and grammar skills.

Why join us?

We hire the best, develop ourselves and each other, and recognize the power of being one team! We understand that you will want to grow both professionally and personally throughout your career, and therefore at you will benefit from an , ensuring you reach your potential.

What we Offer:

As well as being rewarded a competitive salary, we have an extensive benefits package based around the health and well-being of our employees. We have a , where we truly value a work-life balance. We've grown sustainably year on year but continue to offer a collaborative environment, with teams of colleagues eager to share expertise and have fun together. We are a global organization but with a local feel.

Our Mission is to enable our customers to make the world healthier, cleaner and safer.

Watch as our colleagues explain 5 reasons to work with us. As one team of 100,000+

colleagues, we share a common set of values - Integrity, Intensity, Innovation and Involvement - working together to accelerate research, solve complex scientific challenges, drive technological innovation and support patients in need. #StartYourStory with PPD, part of Thermo Fisher Scientific, where diverse experiences, backgrounds and perspectives are valued.

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