Principal Clinical Research Associate

Company Description

CareDx, Inc., headquartered in Brisbane, California, is a global molecular diagnostics company focused on the discovery, development and commercialization of clinically differentiated, high-value diagnostic solutions for transplant patients. CareDx offers AlloMap®, a gene expression test that aids clinicians in identifying heart transplant patients with stable graft function who have a low probability of moderate to severe acute cellular rejection. CareDx is developing additional products for transplant monitoring using a variety of technologies, including AlloSure®, a proprietary next-generation sequencing–based test to detect donor-derived cell-free DNA after transplantation.

CareDx, with its presence through Olerup, also develops, manufactures, markets and sells high quality products that increase the chance of successful transplants by facilitating a better match between a donor and a recipient of stem cells and organs. Olerup SSP® is a set of HLA typing used prior to hematopoietic stem cell/bone marrow transplantation and organ transplantation. XM-ONE® is the first standardized test that quickly identifies a patient's antigens against HLA Class I, Class II or antibodies against a donor's endothelium. For more information, please visit: www.CareDx.com.

Job Description

In this position the principal CRA will play a key role in supporting the design, managing the implementation and conduct of the next stage of state-of-the-art clinical utility prospective multicenter trial(s) that may help change the standard of care and improve patient outcomes in renal transplantation. The candidate will provide direction and operational leadership of the clinical research studies to ensure delivery on time, within budget, and of high-quality in compliance with ICH GCP, Internal SOPs and all other applicable regulations. The Principal CRA should be a critical thinker and capable of problem solving and aligning the priorities with study outcomes and timelines. A good candidate should demonstrate clinical development experience of the operational aspects of all stages of clinical studies preferably working in and/or monitoring or leading affiliate teams, working with vendors and/or CROs, study supply management and planning operational activities to achieve database lock.

Specific responsibilities include, but are not limited to:
Interaction with Clinical Sites

- Attend procedures to support sites (e.g. provide guidance on case report form [CRF] completion)
- Collect data/observations, and obtain product development feedback.
- Interact directly with clinical sites, including clinical investigators and other health care professionals involved in the clinical study

- Conduct site visits (e.g., site selection visits, pre-study site visits, training visits, site initiation visits, interim site visits, and study close-out visits), as required.

Project Management

- Develops operational plans including site monitoring strategies, risk mitigation strategies, trial budgets, site selection, and clinical supplies management.
- Develops and maintains effective working relationships with multiple teams, external CRO (for outsourced teams) and co-development partner study teams.
- In collaboration with functional management, coaches, mentors, supports, and provides study specific direction to team members.
- Oversees the development and maintenance of study specific manuals.
- Contributes to the development and management of the study timelines, resources, budget, risk and quality plans.
- Contributes to study management of new and ongoing studies.
- Establishes study milestones and ensures accurate tracking and reporting of study metrics.
- Ensures operational tracking tools are identified, including systems to meet the needs of the operations team.
- Provides operational input into the development of protocol feasibility questionnaires.

Communication:

- Act as a liaison (directly or via supervision of CRA(s)) between our company and clinical sites.
- Generate clear and concise trip reports, site contact documentation, monthly status reports (e.g., enrollment, adverse events, budget, etc.) and clinical summaries.
- Maintain study documentation (e.g., correspondence, CRFs, deviations, budget information).
- Serve as a clinical resource to other departments at our company to support product design, development and marketing efforts.

Regulatory

- Monitor activities at clinical study sites to ensure compliance with Good Clinical Practices (GCPs), IDE, SOPs, and study protocols.
- Assist in generation of protocols, CRFs, Informed Consent documents, Instructions for Use Manuals, and site training materials for pre- and post-market studies.

Study Administration

- Ensure clinical studies are conducted in a timely manner and within site budgets
- Assist in preparation of reports for submission to regulatory agencies.

Financial

- Develops and manages clinical study budgets (including HQ budget) and contributes to staffing/resourcing plans.
- Communicates variances in the budget and action plan for resolution.

People

- In collaboration with Chief Medical Officer, assist in building effective and efficient high performing operations teams and ensures team members are aware of their accountabilities, responsibilities and deliverables.
- Creates team culture and promotes team spirit.

Qualifications

- Degree/certification in life sciences, health sciences or equivalent degree/experience (e.g., BS, RN, RT)

- 6 years experience implementing and monitoring clinical studies preferably involving diagnostics tests.
- Proficient in FDA regulations for clinical studies and medical devices, including GCPs.
- Working knowledge of medical terminology.
- Experience with medical laboratory testing and documentation of patient information.
- Comfortable with technology and scientific/engineering principles.
- Excellent knowledge of MS Word, PPT and good knowledge of MS Excel.
- Strong project management, documentation, and organizational skills
- Must be detail- and accuracy-oriented.
- Must have high standards for quality of work.
- Strong verbal communication skills and effective writing skills.
- Successful history in a team-oriented environment yet able to work independently.
- Must have a sense of urgency about problem-solving and completing projects.

Skills and Experience:

Proven clinical development experience of the operational aspects of all stages of clinical studies preferably working in and/or monitoring or leading affiliate teams, working with vendors and/or CROs, study supply management and planning operational activities to achieve database lock. Experience of project managing operational aspects of a clinical study including development of timelines, budgets and resource plans. Good knowledge of ICH GCP Proven ability to successfully achieve results within a diverse team and in a fast-paced, high-intensity environment. Experience of working as part of a study or functional teams, with a proven ability to be an active member of the team and motivate and lead a small team to deliver against commitments. Well developed written and verbal communication skills demonstrated by ability to present clear instruction/direction to teams at the same level in the organization and influence at higher levels in the organization.

SCOPE OF WORK

- Travel estimate 20-40% .
- Operate within standard guidelines, but must engage in some independent decision-making.
- Errors that are not quickly detected and rectified could have a significantly adverse effect on the quality of the study.
- Works closely with other Clinical Research staff, as well as staff from other departments.

PREFERENCES

- Experience with clinical studies involving organ transplantation.

****To Apply:** Please send cover letter and resume to HR@CareDx.com

Staffing Agencies and Recruiters

We appreciate your interest in CareDx, Inc. To develop a working relationship with us, we ask that you please contact our Human Resources Dept. at HR@CareDx.com.

All employment openings are managed through our Human Resources Dept. The CareDx, Inc. hiring managers and employees will not accept unsolicited resumes from any source. Submission of unsolicited resumes in advance of an agreement between the Human Resources Dept. and the recruiter does not create any implied obligation on the part of CareDx, Inc.

Therefore, we request that recruiters do not contact employees directly in an attempt to present candidates We thank you in advance for your cooperation, and look forward to possible job search collaboration in the future!